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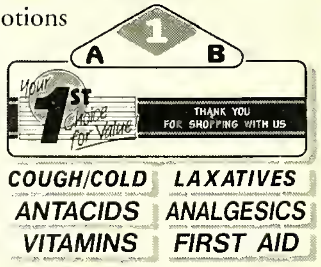

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Cover

*A quiet Winter's day at Carver's Gap on Roan Mountain. Photo by Sandra Depew, Morganton, NC.*

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Daniel G. Garrett
Executive Director

# "...for the Benefit of Society."

Pharmacy is in the news. This is not a good sign. The media mostly reports problems that attract public attention and can be sensationalized. The Wall Street Journal recently ran a weeklong series starting with the line, "America has a new drug problem." The focus of the series was the dramatically increasing costs of medications. North Carolina newspapers and television stations have covered in detail the problems of medication errors, high costs of drugs and the Board of Pharmacy's regulations on pharmacists' work hours and breaks. The pharmacy magazines have reported the results of the New York state pharmacist satisfaction survey, painting a bleak picture of working conditions for those who practice in our profession. In New York, 65 percent of the pharmacist respondents indicated that they would not choose pharmacy if they were beginning college today.

Despite the negative press and dissatisfaction among pharmacists, the Gallup poll has rated pharmacy as the most respected profession for the tenth straight year, and 64 percent of the public placed pharmacists at the top. We have earned the public's respect through years of caring for individual patients. I think we are on the verge of losing this reputation if we continue to practice pharmacy with a fast food mentality and don't restore our personal service focus.

The NCPhA Executive Committee discussed many of the issues being raised locally and nationally at their last meeting. The bottom line question is, "What can be done to improve working conditions for pharmacists?" I was asked to call the people in New York to find out what strategies they were formulating as a result of their survey. New York is considering asking its Board of Pharmacy to limit the number of prescriptions dispensed per hour, look into labor laws to require breaks, discuss workplace concerns with chain management, create a PPO to negotiate dispensing contracts with third parties and form a union. I am not satisfied with these strategies. They leave out the reason our profession exists: the patient!

We are fortunate in North Carolina to have a Board of Pharmacy that has the courage to be the first in the country to require the reporting of medication error related deaths, limit the number of prescriptions dispensed per hour and propose regulations limiting work hours and requiring breaks. This is only the beginning, and the Board of Pharmacy is not responsible for pharmacy working conditions. This responsibility belongs to individual pharmacists. Pharmacists must recognize their professional obligations, openly present their concerns to employers and refuse to sign contracts which sell prescriptions at a loss. Unions do not have a place in the profession. Unions don't care for patients. The mission of our new unified pharmacy organization is to "unite, serve and advance the profession of pharmacy for the benefit of society."

What are we doing in North Carolina to better position pharmacy to care for patients? This question is being answered across our state by individual pharmacists. Here are a few examples:

- **Pam Earnhardt** in Greensboro is working with CVS corporate management to establish a model clinical practice for their chain.

- **Kristie Johnson**, **Tom Mansbery** and **Chris Bowen** in Chapel Hill have worked with Kerr Drug to establish an enhanced pharmaceutical care center.

- **Neil McPhail** and **Dena Askew** in Erwin are working with Erwin Mills to implement a diabetes care program.

- **Henry Herring** and **Beverly Clark** in Wilmington are working with an insurance company to provide pharmacy managed wellness benefits for local employers.

- **Gil Ripley** and **Jesse Crosswhite** of Elkin are providing leadership in their community to implement pharmacy services for the indigent and a disease management network.

- **Michelle** and **Philip Bozovich** in Greensboro have established a patient care model pharmacy.

- **Peter Gal** and **Larry Long** have helped organize a group in Greensboro into the first pharmacist IPA for cognitive services in the state.

- **Joe Edwards** of Raleigh is leading the effort to form a statewide pharmacist PPO for reimbursement for pharmaceutical care.

- **John Butts** of Chapel Hill is facilitating the North Carolina Center for Pharmaceutical Care Certificate review committee to update standards and renewal of credentials for disease management.

- **Mike James** of Raleigh, **Ken Burleson** of Hickory and **Frank Burton** of Greensboro are preparing us for the 1999-2000 legislative session and are optimistic about the opportunity to pass the Collaborative Practice Act and Bill 866.

- **Ron Small** of Winston-Salem, **Chris Dooley** of Greensboro, **Bill Horton** of Asheville, **Joe Moose** of Concord and **Bill Campbell** of Chapel Hill have agreed to serve on a task force with five physicians from the Medical Society to develop the parameters for collaborative practice.

I have intentionally listed these pharmacists simply by their names and home towns (no titles or degrees.) They are real people who have decided to take actions to improve pharmacy practice. Their collective attitude is best summarized by one person who told me, "I try to do what is best for my profession and my patients." Practicing by this principle will result in fewer headlines, and pharmacists will continue to lead the Gallup poll.

# Statewide Pharmacists' Network In the Works

by Joe Edwards
Edwards Pharmacy
Raleigh, NC

When we as pharmacists take a serious look at pharmaceutical care, we have to understand that we are in an evolutionary process. What started as a dream in North Carolina in 1993 is about to become a reality in 1999 with the formation of a strong statewide network along with a network of local provider groups. We have evolved into an information-based profession with pharmacists as primary health care providers. Whether we are providing patient education, developing therapeutic protocols, consulting long-term care or monitoring compliance, pharmacists are committing to comprehensive patient management. Patients and payers win with lower overall health care costs.

Given these dynamics of practice, we must realize that there are many pieces to the pharmaceutical care puzzle which are falling into place as we begin the formal process of network development.

1. We need a core group of pharmacists who are leaders in our cause. What began as the "Pharmaceutical Care and Compensation Committee" under Jean Douglas has developed into the North Carolina Center for Pharmaceutical Care led by Fred Eckel. These groups have been the driving force in incubating our project.

2. We need a strong demonstration project. Thanks to Dan Garrett, Bill Horton and all the western North Carolina providers, we have proven the value of pharmaceutical care through the Asheville Project.

3. We need to have a number of local pharmacy networks to form at the grassroots level. Greensboro is well on its way with Asheville, Raleigh-Durham, Wilmington and others soon to follow.

4. We need individual pharmacists to be successful in providing pharmaceutical care. Jennifer Burch, Michelle Bozovich and many others have been pioneers in breaking through the maze of regulations and billing barriers.

5. We need legislative authority to practice at the next level. We have been successful in having "direct reimbursement to pharmacists" implemented. We must now demand "drug administration" and all "collaborative practice agreements" legislation in the next legislative session.

6. We need a broad-based training program for providing pharmaceutical care. Steve Caiola and the AHEC pharmacy directors are meeting to develop certification programs and educational opportunities in this area.

We have been on a deliberate yet complex journey. The puzzle pieces are finally falling into place, and it is time to make pharmaceutical care happen in North Carolina. We can study the organization and successes of other states, but we must develop the North Carolina model. The following is the chronology of events that have occurred in developing a statewide network.

## Time Line

June 19, 1998 — NCCPC held a conference to discuss forming a North Carolina pharmacy network.

August 20, 1998 — A core group of pharmacists from the June conference met to discuss the feasibility of a statewide network. An implementation statement was adopted: "Pharmacists in North Carolina will form a for-profit preferred provider organization or other entity with a ten-member board of directors, seven of whom must be pharmacists, elected by shareholders. The proposed initial offering will be 250 shares at $1,000 per share. A shareholder may purchase up to 25 shares.

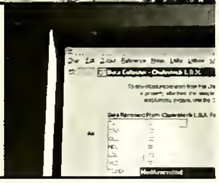
October 15, 1998 — Presentations were made on the statewide pharmacy network to the NCPhA/NCSHP Pharmacy Unification Planning meeting.

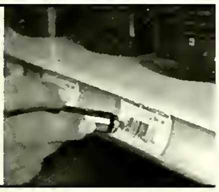
Sept./Oct./Nov. — Negotiations were held with several law firms to go forward with organizational structure.

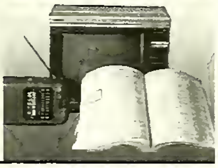
November 5, 1998 — Meetings were held with Larry Long and the Greensboro network to interview legal counsel and develop a loose framework for the relationship between the local and statewide networks.

In early January, a group of pharmacists will meet to develop the organizational structure to have in place and operational by May 1999. We need leadership. We need dedicated providers. We need financial support. And, we need broad-based enthusiasm. A new day is dawning, and it is very exciting. Get on board and help make it happen.

**Contact Dan Garrett at 1-800-852-7343 for more information.**







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# PHARMACEUTICAL CARE: THE NEW ZEALAND EXPERIENCE

by John P. Shaw, PhD, MPS
School of Pharmacy,
University of Otago, Dunedin, New Zealand
(Visiting Scholar, School of Pharmacy,
University of North Carolina at Chapel Hill)

Pharmaceutical care originated in the United States, but it is fast becoming a global practice. Worldwide, patients are seeking assistance to achieve the best outcomes from their medication. At the same time, governments and third party payers are attempting to contain their escalating pharmaceutical costs. Local circumstances will inevitably dictate policies and practices, but in every country there is a vast unmet need for pharmaceutical care and an increasing number of pharmacists willing to provide it. (This article describes the New Zealand experience of pharmaceutical care and progress towards its implementation. The article was written while the author was on study-leave at the University of North Carolina, and this allowed the opportunity to compare progress in these two locations.)

## Pharmacy in New Zealand

New Zealand is a South Pacific nation with a land area about the size of California. The population is 3.7 million people (and about 50 million sheep!). There are about 1,050 community pharmacies distributed throughout the country, with a slightly higher concentration in the major urban areas. All community pharmacies are independent, and there are no chain pharmacies. Many pharmacies have banded together in two or three large franchises which offer buying rights, but they are still owner-operated. This may not be the case indefinitely as the government is pressing for deregulation, and it appears inevitable that this will occur within the next few years.

Until recently, the country had a national health service. This has been subject to enormous change over the past decade, and a number of traditionally "free" services are now subject to various co-payments and restrictions. There has been growth in private health insurance, especially to cover areas such as elective surgery. The current situation might be best described as a "modified national health service."

The Health Funding Authority (HFA) is the government agency which purchases health services on behalf of the public. Providers (hospitals, physicians, pharmacists, physical therapists, etc.) contract with HFA to provide defined services. In the case of pharmacy, community pharmacies contract to provide dispensing and other professional services at fixed rates. For an average pharmacy, perhaps half its income will be derived from HFA contracts with the balance deriving from over-the-counter medicine sales, photography, cosmetics and so on. This income mix varies according to the location and orientation of the pharmacy.

There is a capped national pharmaceutical budget (currently around US$400 million per annum) which covers drug prices and pharmacists' fees. Patients pay a US$7.50 co-payment per prescription item, although there are numerous and complex exemptions and reductions according to age, chronic illness, income level and other criteria. Pharmacists are not currently reimbursed for pharmaceutical care services, but some other "cognitive" services such as medication review in rest homes are covered. HFA has demonstrated a willingness to consider payment for pharmaceutical care if sufficient evidence of effective-

### Box 1

### Medicines Classification in New Zealand

**Prescription Medicines** — e.g. antibiotics, anticonvulsants, antihypertensives, cytotoxics

**Pharmacist-Only Medicines** — e.g. vaginal antifungals, oral NSAIDs, acyclovir cream, corticosteroid nasal sprays

**Pharmacy-Only Medicines** — e.g. topical NSAIDs, oral antihistamines, oral ibuprofen, histamine 2 antagonists

**General Sales Medicines** — e.g. acetaminophen (maximum pack size 20), some antacids

ness is forthcoming.

Medicines classification differs markedly in the United States and New Zealand (refer to Box 1). Pharmacist-Only Medicines must be sold personally by a pharmacist with appropriate consultation and the sale recorded, while Pharmacy-Only Medicines must be sold in a pharmacy under the overall supervision of a pharmacist (but not necessarily by the pharmacist personally). The list of General Sales Medicines which can be purchased from other retail outlets (e.g. supermarkets) is quite limited. The existence of these third and fourth classes of medicines puts pharmacists in a privileged position with exclusive control of a large number of products, including an increasing number switched from prescription status in recent years. The Pharmaceutical Society of New Zealand (PSNZ), which is the professional registration body of which all pharmacists are members, coordinates a Self Care© project which promotes the advisory and OTC prescribing roles of pharmacists. The program is based on self-care fact sheets on a variety of topics (e.g. headache/migraine, vaginal thrush) that the pharmacist can use with the patient. These are backed up with educational material which is updated regularly. In addition, PSNZ field educators visit each pharmacy two or three times a year.

## Pharmaceutical Care in New Zealand

Despite, or perhaps because of, its comparative geographical isolation, New Zealand pharmacy is very active in observing developments elsewhere. Although education and practice is based on traditional links with the United Kingdom, there has always been considerable interest in the American situation. New Zealand pharmacists recognized the significance of pharmaceutical care at an early stage and as a result of interest in his landmark paper with Linda Strand[1], Charles D. Hepler was invited to address the New Zealand College of Pharmacists' Conference in 1992. He threw down a challenge to pharmacists to consider the deficiencies of the traditional drug-use process and to move towards the practice of pharmaceutical care. A succession of leading American visitors continued the theme in subsequent years including Timothy Webster in 1994, Linda Strand and Peter Morley in 1995 and Calvin Knowlton in 1996.

PSNZ sent study teams to the United States in 1994 and 1995. They looked at a number of models of pharmaceutical care and eventually determined that the Minnesota Pharmaceutical Care Demonstration Project was the closest to New Zealand's needs. This is a "generalist" model where the pharmacist assumes responsibility for all of the patient's drug needs, then moves to specialize based on the specific needs of patients[2]. PSNZ formed a unit entitled the Comprehensive Pharmaceutical Care (CPC) Project under the direction of a pharmaceutical care advocate and pioneer John Dunlop. In 1996, one of the Minnesota Project practitioners, Dr. Brian Isetts, toured New Zealand to assist individual pharmacies in their efforts to set up pharmaceutical care practices[3].

In mid-1996, the first formal training programs for pharmaceutical care were offered. Together with its Australian colleagues, PSNZ had secured the rights to the APhA-developed training program "Positioning Your Practice for Pharmaceutical Care: An Individual Blueprint for Change." This is a five-day program which takes pharmacists through all aspects of pharmaceutical care practice including workplace/workforce changes, documentation, care-planning, billing and so on. Inaugural sessions were held in Melbourne and Sydney in July 1996 and subsequently in other major centers throughout Australia and New Zealand.

At the present time, some 200 pharmacists in New Zealand have undertaken this training program. In addition to the course, pharmacists receive back-up from the CPC Project team in the form of care-plan review and targeted educational services. (Having taken the training course myself, I can attest that it is very good.) There are, however, some difficulties. The course is expensive (although costs have come down) and, despite attempts to customize it, many pharmacists find it difficult to translate the "American" orientation to local practice.

A number of pharmacists have attempted to develop pharmaceutical care services, and some have been very successful. But the obstacles, as in the United States, are many[4]. The list of barriers is much the same in the two countries — lack of time, relations with physicians, remuneration and so on. The key issue for many pharmacists is remuneration: who is going to pay for pharmaceutical care services?

In contrast to the United States with its myriad of third party payers, there are only two potential payers in New Zealand: the government through HFA or the patients themselves. Until the present time, pharmacists have had no option but to charge patients directly. When pharmacists have billed patients, they have been surprised to find that many are very happy to pay for these services. Many pharmacists, however, feel uncomfortable in passing on costs to patients directly. HFA has shown a willingness to consider payment for enhanced pharmacy services, but is itself charged with containing costs within an already inadequate budget. Not unreasonably, it requires more evidence of the benefits of pharmaceutical care before committing to financial support.

## Otago/Southland CPC Demonstration Project

In order to provide further evidence of the effectiveness of pharmaceutical care, the School of Pharmacy at the University of

Otago approached HFA in 1996 with a proposal to mount a community pharmacy demonstration project. This is the only pharmacy school in New Zealand, located at Dunedin on the South Island. After prolonged negotiations, the HFA agreed to fund the project with additional financial support provided by GlaxoWellcome (New Zealand) Ltd. Asthma was chosen as the disease model. Five community pharmacies in small rural towns in the provinces of Otago and Southland, close to Dunedin, agreed to participate. The basic structure of the project was that each pharmacy would recruit 20 asthma patients over a two year period. The patients would receive CPC services from these pharmacies, and outcomes would be tracked by the project team at the School of Pharmacy.

The project commenced in May 1997. Great pains were taken to ensure the support and involvement of local family physicians (general practitioners), respiratory specialists, asthma nurse educators and other interested parties. Patients gave informed consent to participate and recruitment took place in consultation with their general practitioners; their asthma was rated as moderate to severe. The full spectrum of ages was included, from children to teenagers to adults. Before patient recruitment commenced, the pharmacists undertook an intensive education program in asthma management and the CPC process coordinated by the research team. This included self-study materials and three full training days. The documentation system used was a modified version of the Cognicare© software from Carepoint© (South Carolina). The CPC process employed by the pharmacists was based on the Minnesota Project (see Box 2).

In this project, a combination of clinical, economic and quality of life outcome measures was used (see Box 3).

At the time of writing, the project was halfway completed with 50 patients enrolled and receiving pharmaceutical care. Two further cohorts of 25 patients are being recruited and phased into the study at four month intervals. The results will be reported elsewhere on completion, but the project has already been a resounding success.

All of the patients in the study to date have had unresolved medication problems. The most common findings have been poor understanding of asthma, overuse of reliever medication, under-use of preventer medication and lack of an action plan. These issues have surfaced repeatedly, even in patients who have received treatment for many years. No one is to blame for these problems, but they reinforce our belief that there is a major societal problem with the current drug use process and an untapped need for pharmaceutical care. Using criteria we have developed to assess the outcomes of the CPC intervention, it is our estimate that 40 percent of these patients have experienced a major improvement in asthma management, 35 percent a moderate improvement and 25 percent little or no improvement. Both generic and disease-specific quality of life scores have shown statistically significant increases. The economic data has been difficult to disaggregate. It is likely that there will be large downstream savings but modest increases in pharmaceutical costs.

### Box 2
### Comprehensive Pharmaceutical Care Process

1. Gather detailed information from patient interview, respiratory function tests, prescription records, etc.

2. **Evaluate and identify** actual and potential medication-related problems.

3. **Devise** Care Plan with specific outcomes and monitoring procedures.

4. **Implement** elements of the Care Plan in consultation with the patient.

5. **Monitor** outcomes at appropriate intervals and modify Care Plan accordingly.

### Box 3
### CPC Project Outcome Measures

- Medication use (e.g. average bronchodilator/ corticosteroid puffs per day)
- PEFR records
- Symptom diary
- Adherence to Action Plan
- Hospitalizations/ER visits/General practitioner visits
- Days off work/school
- Generic quality of life (Short Form 36)
- Specific quality of life (Asthma Quality of Life Questionnaire)

## Observations and Comparisons to Asheville Project

Some issues concerning the Otago/Southland CPC Project merit further comment. First, the pharmacists who agreed to participate (with the exception of one) had no previous experience of pharmaceutical care. They had all been qualified for at least ten years, with three of them in the "golden oldie" category. The point here is that we were enormously impressed with the enthusiasm and ability of these "typical" community pharmacists to respond successfully to this challenging new practice. Second, it is important to note that the pharmacists were paid to undertake these services through contracts with HFA. The sums involved were adequate to compensate for time not spent on other duties. We believe that this establishes an important precedent in attempting to secure further government funding for pharmaceutical care services. Third, both pharmacists and patients expressed great satisfaction with the service and supported its wider implementation. Even those general practitioners who were initially ambivalent have grown to be supportive.

In attempting to compare and contrast progress with pharmaceutical care in New Zealand and North Carolina, one is struck by the similarities rather than the differences. The parallels between the Otago/Southland CPC Project and the Asheville Project in western North Carolina are uncanny[5]. The projects started at much the same time and use near identical protocols and methodologies, and both have the support of a single major funder. The New Zealand project started with asthma as the model, and there are plans to expand the project to diabetes; Asheville used the reverse order.

In a wider sense, the parallels continue. Although the environment in which pharmacy is practiced in the two locations is very different in many respects, the opportunities and barriers for the implementation of pharmaceutical care are much the same. To return to the opening comments of this article, there is a universal need for pharmaceutical care services if medication use in our societies is to be improved and costs contained. Everywhere, pharmacists are ready, willing and able to respond to the challenge. What is urgently required now is the evidence to convince those who hold the purse-strings that this is an investment worth making. It is gratifying to know that around the globe such evidence is accumulating.

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*Pharmacists: Ann and Mark LaHood, Mike Kirby, Bernie McKone, Jim Tattersfield, Denis Todd.*
*Otago Research Team: Peter Barron, Gordon Becket, Lynne Emmerton, Nadir Kheir, Nerida Smith*

**About the Author**

John Shaw teaches clinical pharmacy and pharmacy practice at the School of Pharmacy, University of Otago, and is Associate Dean for Academic Affairs. He is Principal Investigator for the Otago/Southland Comprehensive Pharmaceutical Care Demonstration Project. He is currently on sabbatical leave at the School of Pharmacy, University of North Carolina (Chapel Hill).

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# The Pharmacy Unification Task Force on Education — Where Are We Going?

by Steve Caiola
Director of Postgraduate Education and Training

What are we doing through postgraduate/continuing education to assist our members in developing and maintaining vital, thriving practices? The Driving Committee leading the unification of our statewide professional organizations has directed the Education Task Force to answer this question and chart appropriate directions. The Task Force consists of 17 pharmacists, two students, two technicians and two CE staff/meeting planners, and it represents NCPhA, NCSHP, NCASCP, NCRPhA and the Schools of Pharmacy at Campbell and UNC. Anna Garrett serves as chair, and Margaret Sgritta is liaison to the Driving Committee.

### Task Force Purposes and Progress

At its first meeting on Oct. 17, 1998, the Task Force defined its purposes as: Assuring that educational activities meet the needs of all practitioners; Planning an educational calendar to meet all practitioners' needs; and Supporting local/regional educational programming. At its Nov. 20 meeting, the Task Force evaluated the breadth of needs of all potential members. The Task Force believes that pharmacists attend professional meetings for five reasons: 1) For education and skill training in contemporary pharmacotherapy and pharmaceutical care; 2) To meet their colleagues and share professional experiences (professional networking); 3) For social interaction (receptions, meals and free time); 4) To learn about and shape policy and socio-political issues that affect pharmacy practice; 5) To meet with vendors (exhibit program).

All future statewide meetings will address each of these needs to varying degrees. Every meeting will include education, social interaction and vendor contacts. The North Carolina Pharmacy Annual Convention will be the meeting primarily concerned with shaping policy, though every meeting likely will deal with learning about some political and policy issues.

Also, the Task Force proposed an annual calendar and the general educational content for each statewide meeting. Statewide meetings will be co-sponsored jointly by the new unified organization and the state's two pharmacy schools, all of which will be actively involved in planning and presenting educational content.

### Pharmacists' Education within the New Unified Organization

Professional and administrative staff time is formally being dedicated to practitioner education. At the Institute of Pharmacy, Cathy Jordan has been named Meetings Coordinator and is dedicated to this activity in her 3/4 time position. Steve Caiola, as a component of his position as Director of Postgraduate Education at the UNC-CH School of Pharmacy, also serves part-time as Director of Postgraduate Education and Training for the unified organization.

The new organization will be committed to supporting the full spectrum of postgraduate education for practitioners - from local meetings to residency programs. It will work directly with local associations and the regional AHECs in assisting with local, "traditional" programs. State association officers and board members will be available to attend local association meetings. These elected leaders will share what's going on at the statewide level, respond to questions and learn what practitioners think and want. The AHECs and Schools of Pharmacy will work with the organization and assist with program structure, content and speaker identification. It will manage the existing Continuing Pharmacy Education process that reviews and approves local programs as acceptable to our state's Board of Pharmacy, and also facilitate certificate education and training programs through the AHECs and the North Carolina Center for Pharmaceutical Care (NCCPC).

### Statewide Meetings for 1999

For the next few years, the statewide organization plans to sponsor four meetings. In 1999, the meetings and their content will be:

- Feb. 11-12: The North Carolina Pharmacy Winter Meeting - The unification process; workshops on pharmaceutical care topics
- May 20-23: The North Carolina Pharmacy Annual Convention - Reimbursement for pharmaceutical care services; regional and statewide pharmacy network formation; pharmaceutical care workshops; organizational policy and politics; review for the Board of Pharmacy examination
- Sept. 11-12: The North Carolina Pharmacy Practice Seminar - Community pharmacy practice and pharmaceutical care; workshops on pharmaceutical care topics
- Oct. 6-7: The Annual Carolina Seminar - Health-system pharmacy practice and pharmaceutical care; acute and chronic pharmacotherapy issues

Beginning in the year 2000, the Task Force proposes that the North Carolina Pharmacy Winter Meeting focuses on long-term care and ambulatory care practice, pharmaceutical care and pharmacotherapy issues. The North Carolina Pharmacy Annual Convention should focus on policy formation, review and approval; political issues; general pharmacy practice, pharmaceutical care and pharmacotherapy issues. The North Carolina Pharmacy Practice Seminar and the Annual Carolina Seminar will remain the same. If possible, all meetings should include small group workshops with hands-on experiences. Also, components of certificate training and certificate renewal programs should be included with statewide meetings.

### We Need to Hear from YOU!

The Education Task Force believes it has major responsibilities in guiding the new statewide organization in fulfilling its mission "to unite, serve and advance the profession of pharmacy for the benefit of society." Its work has just begun. Please write, call, fax or e-mail the Institute with your thoughts, criticism and suggestions regarding what the Task Force can do to help the profession thrive!

# Practice Profile

**Central Pharmacy**
2609 N. Duke St., Suite 103
Durham, NC 27704
Phone: 919-220-5121

- Bill Burch, BS, RPh, FACA, Owner, UNC 1970
- Jennifer Burch, PharmD, RPh, CDE, Campbell 1993

Email:whburch@aol.com; jeburch@aol.com

Number of employees: 6 Pharmacists: 2.2 and Techs: 2.6

Population served: Acute and chronically ill patients who desire a high level of service from their pharmacists.

*1. Briefly describe your overall practice.*

Central Pharmacy is an independent pharmacy located inside a physician office park in northern Durham county. It was started in 1977 by owner Bill Burch and has more than doubled in size since then. We provide traditional pharmacy services with limited front end merchandise. We have developed specialty services in areas such as compounding, hospice and disease state monitoring and education services. Due to these specialty services, we serve patients throughout Durham and Orange counties.

*2. What is unique about the patient services you provide?*

We provide asthma, diabetes, hormone replacement, hypertension, lipid and men's health individualized education programs. We started formal programs with these conditions over five years ago. We chose these conditions first due to their prevalence in our practice and the community and the huge costs associated with each. We provide individual appointments and some group classes.

Recently, we had the opportunity to provide disease state monitoring and education to patients inside a large internal medicine practice. We see patients by appointment on Wednesdays that are referred to a pharmacist by a physician for education, monitoring and pharmacotherapy issues.

We have always provided an extensive amount of counseling to patients about their medications. In addition, we have always provided training for blood glucose monitors, insulin injections, nebulizers and blood pressure machines. Due to our excellent reputation for patient education in the medical community, it has been much easier to get physician referrals for our educational services. Our extensive disease education and monitoring grew out of services we were already providing.

*3. How did you determine the need for this service? How did you develop your practice to meet that need?*

To develop our practice, we learned how to be good marketers. We have developed letters and brochures to send the physician community, but find a face to face encounter works the best. We also have information spread throughout the pharmacy for patients to pick up. We use flyers as statements and bag stuffers to continuously remind patients of our services.

Since beginning to provide these services, we have focused a great deal of our continuing education efforts on those specific disease states. We certainly get more than our 10 hours of CE each year in order to stay up to date in these areas. We have both participated in a rigorous Asthma Certificate Program. I (Jennifer) passed the Certified Diabetes Educator exam in Fall of 1997.

*4. Are you being reimbursed for the services you provide?*

We are currently receiving reimbursement for cognitive services from several different sources. Many patients see value in our educational services because it improves their quality of life and reduces long term costs. Patients will pay out of their pockets and can then push their insurance companies to reimburse them for this valuable service they receive. Insurance companies will also pay for cognitive services *but only* if we submit bills to them. We have received checks from Cigna, HealthSource, BCBS, Principal and others who process claims for self-funded plans. The third source that will pay for cognitive services is physician groups. Many physicians welcome our help to manage and monitor their patients. This means the physician sees the patient less, yet, they are still being monitored and managed appropriately. Physicians may see more opportunity for collaboration as capitated insurance plans increase.

*5. What lessons have you learned as a result of this experience?*

We have learned several lessons from our past experiences. One is that you do not have to recreate the wheel to set up a diabetes or asthma program. There is a huge amount of literature available about what people throughout the country are doing. There are also many pharmacists in NC who are providing services that can help advise you in starting a program. The second lesson is that this takes a big commitment to change your practice and develop new services. The third is that physicians are ready to collaborate with pharmacists to improve the quality of care a patient receives.

Providing more patient care is very professionally rewarding. It is a very good feeling to have a patient say, "Thank you," and shake your hand or say, "I feel better than I have in months." These are the days we go home very satisfied with what we are doing.

Financial rewards for cognitive services are slower to be realized. Reimbursement from insurance companies is coming on a more steady basis. Currently, we are working on some local opportunities to provide these services to a much larger population than we now serve.

*6. What were your stumbling blocks?*

Fortunately, we have not run into many stumbling blocks along the way. The largest obstacle we face is to constantly remind the physician community of our services. We must keep our name in front of them weekly, or they forget. This is a challenge due to the time involved with sending letters or having appointments. Marketing is definitely a class we should have had in pharmacy school.

*7. Where are you heading now with your practice?*

Our practice continues to grow each year. Both the prescription volume and the specialty services are increasing. We continue to cultivate the compounding practice because we see tremendous room for expansion in our market. With the continued growth of our disease state education and monitoring services, we would like to be able to obtain some local contracts to provide disease state education and monitoring services. We would definitely like to grow the cognitive services side of the business because there is an enormous opportunity for pharmacists to have an impact on patient care and to be reimbursed for it. We will consider some additional disease states within the next year as necessary with a expanding practice.

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# Cold and Flu

by Carla Schoenberger, PharmD

There are more than 200 different viruses that can cause colds and flu, and these viruses are constantly changing. Treatment can be hard, so prevention is the key. Influenza is rarely dangerous in healthy adults 60 years of age and younger, but it can make a person more susceptible to ear infections, pneumonia and sinus problems. The flu is clearly a serious infection for older people. Among people 65 and older, serious infections such as pneumonia and influenza are the fifth leading cause of death.

Sometimes you just cannot avoid a cold or flu. When the symptoms of chills, fever, cough, achiness and all-over malaise strike, the best advice is to take it easy. That means getting plenty of rest. Now let's discuss how to speed recovery if you do get a cold or the flu.

**Vitamin C** has been proven to be an immune-booster, and is probably the best researched cold-fighter. The consumption of large amounts of Vitamin C (1-4 grams daily) reduces the duration and severity of colds. I recommend to my patients to take 1000 mg three times a day with meals. These high doses (500 mg or more) can produce mild diarrhea or gas in some patients, while others tolerate 8000 mg or more with no side effects. If gastric symptoms are experienced, reduce the dose until they disappear.

**Vitamin A** attacks viruses directly and keeps bacteria and viruses from penetrating protective mucous membranes in the mouth, nose, stomach and lungs. The suggested dose is 15000 IU daily. If you are pregnant, do not exceed 10000 IU daily.

**Zinc** has a key role in general immunity. It is also an antiviral agent, and it inhibits the growth of the common cold virus. This may be why the majority of clinical trials show that sucking on zinc gluconate lozenges reduces the duration and severity of colds. The dosage in successful clinical trials was 23 mg of zinc, taking one every two hours while awake, until the symptoms disappeared. The benefit from zinc lozenges seems to be maximal if started immediately after the onset of symptoms.

**Echinacea**, the purple cone flower, has been used for many years to treat infections. The most popular use today is reducing symptoms of the common cold and flu especially if taken at the onset or in the early stages of infection. Many clinical trials have shown the herb's ability to reduce both the incidence and duration of cold and flu infections. The recommended dosage is 1 gram daily of dried rhizome or roots. Capsules containing the powdered form are available. The dose is divided up and taken three times a day. This herb is also available in tincture form, and 15-30 (0.75-1.5ml) drops can be used two to five times a day. No harmful reactions have been reported when echinacea is used as recommended. This herb should not be taken for more than two weeks at a time. Prolonged administration of echinacea may lead to immune system overstimulation and eventual suppression.

**Garlic** is also an herb that may help cold and flu sufferers. Garlic boosts immune activity by stimulating natural killer (NK) cells. It is most effective when eaten raw, thinly sliced or minced on sandwiches, salads and pasta. One to two cloves per day is the suggested dose.

**Steam inhalations** can be very soothing. You can boil a large pot of water and stand over it with a towel covering your head and the pot (be careful not to catch the towel on fire). Breathe the steam through the nose for nasal and sinus problems. You can add sage and/or eucalyptus (essential oil or dried leaves) to the water, and this will help open up nasal passages more and help keep any secondary (bacterial) infections from taking hold.

Americans spend more than $1 billion every year on nonprescription treatments for colds and flu. These products offer temporary relief of symptoms.

**Analgesics**- i.e.) Acetaminophen, aspirin and ibuprofen will help relieve aches and pains and reduce fever.

**Antihistamines**- i.e.) Chlorpheniramine, brompheniramine, dexbrompheniramine and diphenhydramine decreases nasal secretions by blocking the action of histamine. These products also help stop sneezing and runny noses. They can cause drowsiness.

**Cough medicines**- Two basic types: expectorants (guaifenesin) and antitussives (dextromethorphan). Expectortants make coughs more productive by increasing the amount of phlegm and decreasing its thickness. Antitussives reduce the frequency of coughing. Since coughing is the body's mechanism for clearing secretions from the lung, it is probably best not to suppress the cough unless the coughing is severe or persistent, or is interfering with sleep.

**Decongestants**- i.e.) pseudoephedrine and phenylpropanolamine shrink nasal blood vessels to relieve swelling and congestion.

Many OTC cold medicines have a warning that says: Do not take if you have heart disease, high blood pressure, thyroid disease, diabetes or difficulty in urinating due to enlargement of prostate gland. When I recommend these products, I feel it is very important to make sure I ask about these conditions before I recommend a product.

Winter is the season for colds and flu. Prevention is the key, but we do have products to help relieve symptoms and to boost the immune system, if the flu bug is not prevented. I always tell my patients that this product should help them feel better, but if they have the flu and breathing difficulty persists or they are elderly or immunocompromised, I suggest seeing their doctor.

**Strategies to fend off colds and flu**

- Wash your hands frequently, and try not to touch your face (nose and eyes)
- Try to stay away from people who have respiratory infections (colds and flu are spread in the air from droplets from a sneeze or cough)
- Regular exercise and a balanced diet rich in fruits, vegetables and fiber are very important
- Combine vitamins and herbs, which are immunity boosters, with a balanced diet

**Who should get a flu shot?**

- Elderly people (65 and older)
- People with chronic heart and lung diseases
- Those who suffer from diseases that weaken the immune system (AIDS and cancer)
- Health care professionals

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## Campbell Fights Osteoporosis

Fifteen minutes today could save you many frustrating years of bone loss thanks to a joint venture between Campbell University's School of Pharmacy, Eckerd Drug Co. and Wyeth-Ayerst Laboratories. On Oct. 14th and 22nd, the three organizations joined together in a project to fight osteoporosis by offering free bone density assessment to the general public in two local cities.

The scan - simple and painless. Bone scans consist of a four minute low-powered heel X-ray which compares one's bone density value to population modeled values. The entire process is finished within 15 minutes.

Osteoporosis, a silent deteriorating bone disease, currently affects more than 25,000,000 Americans, and the number rises each year. Eighty percent of this growing number consists solely of women!

"Eckerd, Campbell and the pharmaceutical industry see a great need for osteoporosis education," says Chris Miller, National Account Manager for Wyeth-Ayerst Laboratories. "We see this as a pilot project to raise the level of knowledge about the disease in the communities."

Connie McKenzie, Director of Experiential Programs at Campbell University, said, "People need to understand that osteoporosis is not just a problem for the elderly. Bone density peaks between the ages of 25 and 35. Preventive care and screening, if started soon enough, can prevent the disease from occurring altogether."

Several different factors are associated with the disease including age, ethnicity, family history, diet and lifestyle. Menopause can add significantly to the disease in older women by decreasing estrogen amounts. Without estrogen, cells that remove old bone are more active than the cells that build new bone, leading to a faster rate of bone loss. Bone loss ultimately leads to broken bones and fractures. In fact, one out of every two women and one out of every eight men suffer from osteoporosis-related fractures.

This scan cannot cure osteoporosis if already begun, but knowing the facts can help avoid further deterioration. There was counseling available to help the public understand what future questions to ask their doctor. Finding a treatment that works for each individual helps them maintain a healthy, active lifestyle.

Throughout the Fall semester, pharmacy school students, residents and faculty have also participated in weekly patient care programs at Kerr Drugs in Dunn. A rotating schedule of blood pressure monitoring, glucose measurement, cholesterol determination and "brown bag" prescription reviews began Oct. 6 and were completed Dec. 8. Initiated by Gray Stewart and Mark Gregory of Kerr Drugs, the program introduced and evaluated expanded patient care activities in the community drugstore to those participating individuals.

## Pharmacy Students! Ready to hit the beach?

Then take a break this Spring at the
1999 Annual Convention in Atlantic Beach
on May 20-23.

NCPhA and NCSHP are sponsoring a fun social event and a Board Review just for you. There will be time to network and visit the exhibitions, all within a shell's throw of the beach. A special package deal will be offered to students, so mark your calendars and plan your last hurrah of the year with your classmates.

Call NCPhA at 1-800-852-7343 for details.

## UNC Students Hit Midyear in Vegas

A large number of UNC School of Pharmacy students, faculty and alumni attended the American Society of Health-System Pharmacists (ASHP) 1998 Midyear Meeting, held in Las Vegas. In addition to the usual rounds of meetings and talks, participants got an extra treat, a rare Las Vegas snowfall!

Faculty from the School presented continuing education programs, participated in symposia and interviewed candidates for fellowship and residency positions. UNC attracted top candidates from all over the country, and faculty were kept busy questioning the abundance of applicants.

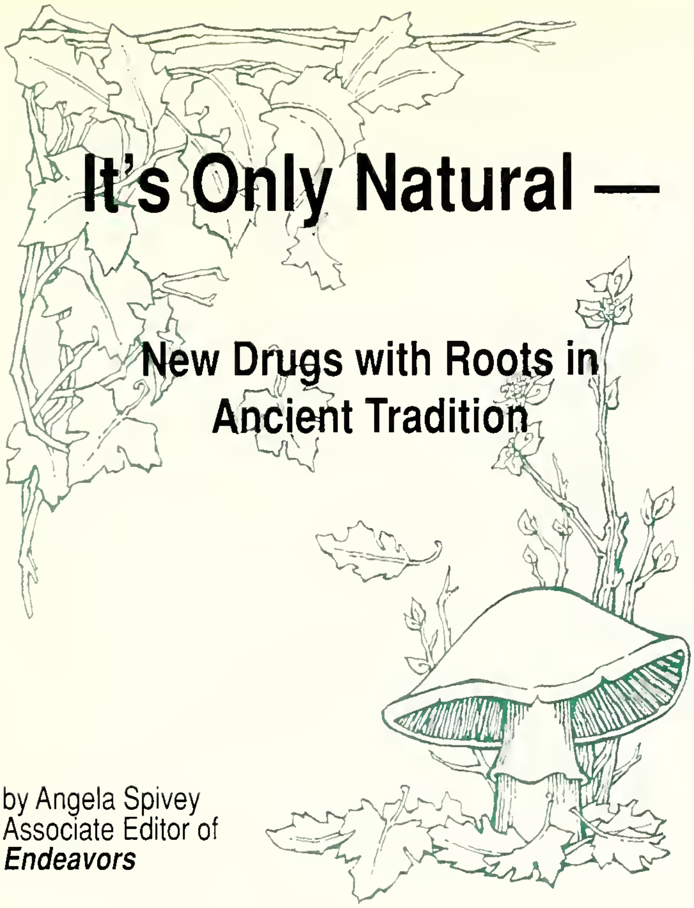
Approximately 60 of the School's professional students made the trip to Vegas. They attended continuing education programs, and a select group participated in a clinical skills competition with other students from around the nation. For many students, this was their first exposure to a professional meeting of this caliber, and most felt they gained good experience from attending.

The Midyear Meeting wasn't all work, however, as students and faculty were treated to dinner at the Motown Cafe in the New York, New York Hotel by Dean Bill Campbell. Dinner guests enjoyed both the delicious food and the live entertainment. Monday night the School also co-hosted a North Carolina reception with NCHSP. The reception provided an opportunity for students, faculty, alumni and other invited guests to get together in a relaxed setting to talk shop and to socialize.

The location for next year's ASHP Midyear Meeting will be Orlando, Fla.

# It's Only Natural —

## New Drugs with Roots in Ancient Tradition



by Angela Spivey
Associate Editor of
***Endeavors***

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Up on the third floor of the UNC-CH pharmacy school, evaporators whir, spectrometers spin. This is the kind of gear people use to make drugs — *serious* medicine. But talk to the 20 medicinal chemists holed up in that bustling lab, and they'll tell you about the mayapple plant, "thunder god vine" or desert parsley. They're discovering serious medicines all right. But they start with plants and herbs. They want to extract their potent parts—compounds or chemicals in the plants that are bioactive—that can, for example, kill cancer cells, viruses or bacteria.

The plants they study are part of everyday life for people in many Asian countries. Most are ingredients in remedies that have been used in traditional Chinese medicine for centuries. K.H. Lee, professor of medicinal chemistry and director of the Natural Products Laboratory, sees traditional Chinese medicine as a head start on finding new, more effective drugs.

"These remedies have been tested for centuries—not in animal assays or in clinical trials, but in centuries of experience of practitioners using them to treat people," Lee says. In some ways, this experiential knowledge more directly applies to humans than the animal testing used to test Western drugs, he says. But many of these remedies lack quality control and have never been evaluated scientifically. And it's often not known exactly which ingredients in a remedy are active.

Lee believes that modernizing and scientifically testing the remedies will help legitimize traditional Chinese medicine so it can benefit a greater number of people. He's constantly pushing for interest from government agencies such as the National Institutes of Health (NIH), and every year he speaks at international conferences on traditional Chinese medicine. This year he's cohosting one in Hong Kong and another in Taiwan.

Lee began studying Chinese medicine partly because his grandfather dabbled in it. When Lee was a boy in Taiwan, his grandfather would take him on trips to gather herbs. "He'd say, 'You want to go with me, I'll show you something.'"

Once Lee saw his grandfather treat a woman suffering from water retention. "Her belly was swollen up," Lee says. "My grandfather picked a handful of elephantopus mollis that was growing underneath some banana trees. He suggested that she boil it with water and drink the juice. After a few hours, that water was expelled.

"When I was young, the herbs were there, and I never paid attention," Lee says. "Later I decided to go to pharmacy school and investigate the active ingredients of these herbs."

Traditional Chinese medicine uses thousands of medicinal plants—so many it could take centuries to investigate them all. But not if Lee has anything to do with it. Since 1971, Lee's Natural Products Lab has discovered more than 1,000 new bio-active natural products and their synthetic derivatives—leads that pharmacologists can use in drug design and development. He also has 10 patents on potential new drugs.

When a visitor walks in Lee's door, "extremely busy" are the first words he utters. Known for his meticulous hard work, he's a machine when it comes to turning out new research ideas. Lee received his first grant from NIH in 1971 and hasn't lost one since. Proudly, he shows off 32 file cabinets filled with records of the lab's work and points out two drawers filled with new ideas.

Lee doesn't seem to mind the long hours. "It's a joy to work in this area because every day you discover something new," he says. "And who knows—a compound that we find may become a drug that will treat disease."

The Natural Products Lab gets plant samples from Brazil, China, Japan and Taiwan as well as the United States. Lee collaborates with more than 60 researchers worldwide. Often his collaborators send him samples, or sometimes people from his lab bring them back when they return from visits home. Most of the lab's 20 visiting professors, postdoctoral fellows, predoctoral graduate students and research faculty are from Taiwan, China or Japan.

> "We are the lab of Martians,"
> Lee jokes.

The lab receives at least one letter a day from a researcher wanting to join them. "Usually, we have to tell them no," Lee says. "All of the people in our lab are the best at what they do or have some special talents."

Lee and his team usually start with a plant used in traditional Chinese medicine, and then they dissect it until they get one or more pure, active compounds. Sitting around Lee's lab are beakers filled with shredded plants soaking in solvent to extract the active ingredients. On another bench an evaporator spins, separating the solvent from the extract. The extract might end up in any form—one beaker contains a thick, dark-brown oil, while the vial next to it holds white granules.

Once they have a plant extract, the researchers find out how many chemical compounds it contains using a procedure called liquid chromatography. In one version, the extract is put into a glass column that's been filled with an absorbent material such as silica gel. Then a solvent is continuously poured down the column, taking the plant extract with it. Since the compounds in the extract have different properties, some will run down the column quickly, and some will stick to the silica gel. This separates the compounds so the researchers can start testing them to see which are the most active.

That's often where Ken Bastow, associate professor of medicinal chemistry, comes in. He collaborates with Lee's lab to test compounds for antitumor ability. Researchers in Bastow's lab grow cells from different kinds of cancer, including drug-resistant varieties, in small tissue-culture plates then add a compound to each plate. After two to three days, they process the plates to see how many cancer cells the compound has destroyed.

When Bastow's lab finds a compound that's particularly good at getting rid of the cancer cells, scientists in Lee's lab use tools such as mass spectrometers and nuclear magnetic resonance spectrometers to find out the compound's chemical structure— how many carbons, hydrogens or nitrogens it contains and its molecular weight.

> "It's like a puzzle," says Susan Morris-Natschke, research assistant professor of medicinal chemistry. "You get information from each different particular piece of instrumentation and put them all together to solve the whole structure."

Once the researchers know what nature has put into the compound, they can try to improve it. "The lab might find that a certain compound is very active against cancer cells, but also will harm normal cells. So they can alter its structure to try to correct that," Morris-Natschke says. "Or they might want to make it even more active." With the help, for example, of a computer modeling lab that's next door to Lee's lab, the researchers can create analogs— compounds based on the original but with slightly different structures.

One analog created by Lee's lab, an antitumor compound, is now in the second phase of human clinical trials. This analog is based on a compound called etoposide that was synthesized years ago from an active ingredient in the American Mandrake or Mayapple plant, which grows under trees in moist open woods. Now used in humans, etoposide is one of the most useful anticancer drugs, Lee says. In 1988, Lee's lab started making etoposide analogs. They made hundreds of them before they came up with the new compound.

Lee's compound improves on etoposide in three ways— it's more potent, less toxic, and it's active against drug-resistant cancer cells which can be a big problem with chemotherapy. Because of the modification that Lee's lab has made, the new compound is not recognized by a protein often found in drug-resistant cells. Since the drug-resistant protein can't recognize the compound, it can't pump it out of the cell.

The compound has been licensed and patented by Genelabs Technologies Inc. From initial studies, it looks like it may be effective against lung, colon and stomach cancers. Lee's lab has created many other anticaner compounds, and the National Cancer Institute has chosen about 100 of them to evaluate as potential anticancer drugs.

The lab also develops leads for drugs to fight HIV. One promising lead is a synthetic compound that in lab tests inhibits replication of the HIV virus better than AZT, a drug commonly used for treating HIV. Lee's lab created this compound by modifying the structure of an extract of the fruits of *Lomatium suksdorfi*, also known as Suksdorf's Desert-parsley, a plant that grows on the U.S. West Coast. This new compound and its analogs are in active studies as anti-AIDS drug candidates.

Another potential anti-HIV drug is neotripterifordin, a compound the lab recently extracted from the roots of a vine that grows in southern China. The root bark of *Tripterygium wilfordii hook*, also called "thunder god vine," is poisonous and is touted as an insecticide in Chinese folklore. After the roots are removed from the bark, they're used in Chinese medicine preparations to treat dermatitis and rheumatoid arthritis. In tissue culture tests, neotripterifordin shows potent anti-HIV activity.

But "thunder god vine" must go through many more tests before we'll know whether it will make a good anti-HIV treatment. It takes a lot of work to find a compound that may actually result in a drug.

"There are many compounds that may look useful in tissue culture, but end up not working," Bastow says. The compound may be effective in animals but not in humans, or it might not be processed well by the body.

That's why Lee's lab is continually sifting through more remedies or tinkering with compounds already discovered. "We provide the lead, a structure that pharmacologists can use as a model," Lee says. Then he gets a license or collaborator to take over further testing, while he moves on to find the next possible new drug.

Demand for drugs and other products derived from plants and herbs has increased, Lee says, especially since 1994, when Congress passed an act that relaxed restrictions on herbal health products. U.S. sales of food supplements or medicines containing such herbs as Ginseng, Dong Gwei and Gingko reach several billion dollars each year. And Lee regularly hears from people at other universities who want to visit his lab or collaborate with him.

As interest in alternative medicine grows, Lee and the other researchers in the Natural Products Lab keep plugging away. They recently signed an agreement with the National Cancer Institute to investigate active plants collected from rain forest areas in many parts of the world. Lee continues to try to increase knowledge of traditional Chinese medicine. And of course, there's always herbs to soak, active compounds to extract and synthesize. As Lee says, "People keep sending us plants."

*The Office of Technology Development (OTD) manages invention licensing and helps form start-up companies based on UNC-CH inventions.*

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# Learning about the Disease of Addiction

by Teresa L. Bryan
PharmD candidate
Campbell University

As a senior at Campbell University School of Pharmacy, I spent the month of September 1998 doing an externship with the North Carolina Pharmacist Recovery Network (NCPRN) and Executive Director Dave Marley. It was a very informative and an eye-opening experience to say the least. I learned about the history and purpose of NCPRN, but in order to fully understand its purpose, I also studied the disease of addiction, chemical dependency and the different aspects of both treatment and recovery.

The first and most important thing to understand is that chemical dependency, whether it be to alcohol, prescription drugs, non-prescription drugs or illicit drugs, is a chronic progressive disease, not a moral weakness. A simple explanation of how addiction develops is that due to genetic, psychosocial and environmental factors, the individual has the idea of trying a particular drug, even though they may be fully aware of the potential dangers. Once their disease of addiction has been triggered, they have to continually rationalize their use of the drugs and essentially develop a sense of denial over what is happening in their life.

In light of this information, the patient can benefit much more from treatment of the disease rather than punishment for having the disease. These individuals did not choose for their addiction to take over their lives, but they can choose to overcome this disease by seeking treatment and establishing and maintaining recovery.

I have also had the opportunity to visit Twin City Counseling Center in Winston-Salem and talk with Certified Substance Abuse Counselors regarding the treatment of individuals suffering from addiction. I was able to observe DWI and substance abuse assessments and discover the skills necessary to perform a complete clinical assessment of these individuals. It was in these situations that I was also allowed to apply the DSM-IV diagnostic criteria which is used in making a diagnosis of substance abuse versus substance dependence. Short and long-term group therapy sessions are also provided as part of the treatment program. I sat in on a session where motivational videos on the importance of a workable recovery and relapse prevention program, as well as group discussions about the warning signs of a relapse filled the agenda. These group sessions, along with individual counseling if necessary, are an integral part of a successful recovery.

Throughout the month, I attended various types of recovery meetings so that I could get some further insight into the thoughts and feelings of individuals suffering from addiction. These meetings included Alcoholics Anonymous, Narcotics Anonymous, International Pharmacists Anonymous and Caduceus meetings. All of these meetings were different in that each one had its own mood and characteristic way of being carried out. But they all have something very important in common — they are a fellowship of men and women in recovery who meet regularly because they need the help and support of others in the same situations to help them stay clean. In these meetings, they learn how to react positively to everyday situations and hopefully stay clean one more day. Resentment, anger and fear are three of the main character defects that are dealt with in the meetings. Instead of being resentful of their past, angry at their present situation and fearful of their future, they can learn to replace these feelings with acceptance of the past, love for the present and faith for the future. With these new ideals working into their lives and the continuing love and support of their fellowship, these individuals are given a new way of life — one that allows them to be clean and sober.

I also read several publications during the course of the month including the Twelve Steps and Twelve Traditions of Alcoholics Anonymous and Alcoholics Anonymous, also known as "The Big Book." This is literature that these individuals learn to live by and incorporate into every aspect of their lives, not just to overcome their disease. Some of the important topics include humility, acceptance, faith, God, honesty and discipline just to name a few. There are also some important slogans found in the readings that are heard frequently during the meetings. These slogans are used as motivational phrases by all members to be able to make it through another 24 hours clean and sober. Some examples include: "Easy does it", "First things First", "Honesty Open-Mindedness and Willingness (HOW)", "Keep coming back", " Live and let live", "One day at a time" and "Turn it over." Belief in a Power "greater than ourselves" and the power of prayer are incorporated into their lives as well. Between their belief in a Higher Power, regular attendance at the meetings, continuing study of the literature and application of its principles to their lives, these individuals now have in place a strong foundation upon which to build their recovery.

Another aspect of treatment and recovery that I observed was in-patient treatment programs both at High Point Behavioral Center and at Fellowship Hall in Greensboro. Patients in these environments learn how to work together with others, improve their social skills, come to terms with their disease and learn how to start their life over without having to use drugs or alcohol. They follow a very scheduled program that includes education on the disease of addiction, introduction to the "Twelve Steps," learning how to use their leisure time wisely and individual and group therapy sessions. They are counseled on how their addiction affects their whole person — their thoughts, emotions and will, as well as physically, socially and emotionally. Then they are introduced to fundamentals of the treatment program that will enable them to overcome their addiction and develop a recovery and relapses program that will work for them and keep them clean.

Interaction with the North Carolina Board of Pharmacy is also an important part of the NCPRN program. The Board and the PRN director have

*Continued on page 26*

NORTH CAROLINA SOCIETY OF HEALTH-SYSTEM
NCSHP
PHARMACISTS
Newsletter

Volume 22, Number 1 The bimonthly publication of the North Carolina Society of Health-System Pharmacists January/February 1999

# New NCSHP Officers Elected to Serve in 1999

**Vance Collins, President-elect**

**Lynne Alexander, Board Member**

**Joe Johnson, Board Member**

Vance E. Collins, Jr., PharmD, is Clinical Coordinator of Pharmacy Services at Halifax Regional Medical Center in Roanoke Rapids. He joined the staff at HRMC upon graduation from UNC in 1987. Vance has served as a Practitioner-Instructor for both UNC and Campbell Schools of Pharmacy and received the Syntex Hospital Pharmacy PI of the Year Award in 1990.

Vance became active in NCSHP in 1985 as a student member. He has served on numerous NCSHP Committees including Communications and Public Relations, Pharmacotherapy SIG Advisory Committees, Awards and Nominations and the Pharmacy Practice Act Committee. He represents NCSHP on the Pharmacy Unification Marketing and Communication Task Force and ASHP's Public Relations Advisory Network. Presently, he is completing a three-year term on the NCSHP Board of Directors.

Vance currently serves on the Area L Pharmacy Advisory Committee and has served as a member of the Board of Directors for the UNC Pharmacy Alumni Association and Regent of Kappa Psi Pharmaceutical Fraternity Beta Xi Chapter.

He is actively involved in community organizations including recently serving as president of the Halifax County Chapter of the American Heart Association. Vance was also recently awarded the community service Jay Harris Youth Award.

Lynne Alexander, MBA, is a graduate of the UNC School of Pharmacy. She completed her MBA in Health-Systems Management at the University of Connecticut in 1989. For the past five years, Lynne has held the position of Assistant Director of Pharmacy, Surgery Services, at Duke University Medical Center. Prior positions include six years as Associate Director of Pharmacy, University of Connecticut Health Center, seven years as Director of Pharmacy, Winsted Memorial Hospital, and staff pharmacist positions in both community and teaching hospitals. While in Connecticut, Lynne held leadership positions in the Connecticut Society of Health-System Pharmacists including chair of the Membership and Finance committees and two terms as treasurer. She also served as chair of the Connecticut Hospital Association (CHA) Pharmacy Directors Conference and vice chair of the CHA Group Purchasing Committee. In NCSHP, Lynne chairs the Administrative SIG and serves on the Program Committee. She is an active member of ASHP as well as the Durham Orange Pharmaceutical Association and the Triangle College of Clinical Pharmacy.

Joseph L. Johnson, BS, is the Director of Pharmacy for the Moses Cone Health System in Greensboro. After graduating from the University of North Carolina at Chapel Hill in 1969, he worked in community retail pharmacy for three years. In 1972, he joined Wesley Long Community Hospital as Director of Pharmacy. Joe served in that capacity until December 1997 when Wesley Long merged with the Moses Cone Health System, and he became Director of Pharmacy over the multi-hospital health system.

Joe has been a practitioner-instructor for UNC-CH pharmacy students for over twenty years and has served on the boards for both NCPhA and NCSHP. He has been active on many pharmacy committees over the past years and has served as president of the Guilford County Pharmaceutical Association.

As an active part of the community, he has served as past president of the Greensboro Diabetes Association and has worked with the Piedmont Ostomy Association.

*Election results continued on page 26.*

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# *Dilemmas*

## Thalidomide: An Old Drug with a New Trick

by Sonia Shaw, PharmD, Rowan Regional Medical Center

After being removed from the European market in the early 1960s, thalidomide has been approved by the Food and Drug Administration (FDA) for use in the United States. Thalidomide was first introduced in 1957, and at that time was considered the safest sedative ever discovered.[1] It was effective in small doses and had no addictive properties or toxicity.[1] Tragically, this was not true. About a year after its release, physicians began to see unusual birth defects in infants born to women who had taken thalidomide during pregnancy.[1] An estimated 12,000 children in Europe and Japan were born before the damaging effects of the drug became known and use was discontinued.[1] These birth defects were so bizarre that a few women abandoned the infants in the hospital.[1] While reduction deformities of the limbs are most readily recognized, thalidomide can cause visceral, facial, spinal and other birth defects such as congenital heart disease, spina bifida and cleft palate.[1]

Even with the bad press from the early sixties, researchers continued to look for new uses for thalidomide. Now, in the nineties, thalidomide is being used in the United States for diseases such as breast and prostate cancer, gliomas, rheumatoid arthritis, AIDS-wasting syndrome, chronic graft-versus-host disease, and its only approved indication, erythema nodosum leprosum.[1] This use is due to controlled clinical trials, an expanded access program, single-patient emergency/compassionate use programs authorized by the FDA[1], and now, the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) program from Celgene Corp.

The S.T.E.P.S. program is described by Celgene as multifaceted and was developed to ensure fetal exposure to thalidomide does not occur. The S.T.E.P.S. program will mean added steps for health-system pharmacists in dispensing this medication to patients. The S.T.E.P.S. program requires physicians, patients and pharmacies be registered to prescribe, use and dispense the medication safely. First, the hospital pharmacy must be registered with Celgene in order to dispense the medication to an in-patient or an out-patient. Second, upon receipt of an initial prescription for thalidomide, the pharmacist must ensure the patient has completed an informed consent form and retain a copy. In addition, the pharmacist must also register or verify registration of the patient in the S.T.E.P.S. program. Then, once the patient is approved to receive the medication, the pharmacist may only dispense a 28-day supply of medication. The medication comes packaged in blister packs with 14 capsules per card and cannot be removed from these cards. Finally, there are two other things the pharmacist must be cognizant of when dispensing a refill of this medication: 1) the patient has less than seven days therapy remaining on their current prescription, and 2) the new prescription was written within the previous seven days.

Experience at our institution with this medication has been laborious. Once we became registered to dispense the medication and dispensed our first prescription, we discovered how confusing the dispensing procedure is. Originally, we called to register the patient. It took about 20 minutes for the phone call and then another hour to receive the fax confirmation of registration. After that, it was only a matter of minutes to dispense the medication. After we dispensed the prescription, we discovered there was one more step to the process. Once the patient is registered as a user, the pharmacist must also verify that they have been approved by the company to take the medication. This can be done either online or by faxing a manual verification form to Celgene. For our second prescription, we completed both the patient registration and manual verification form and faxed them to Celgene. This time it only took about 30 minutes to receive confirmation of registration and approval for the patient to use the medication. For a hospital or retail pharmacy, this is a very labor intensive process to go through to dispense one medication. But, for those patients who need this medication, it is an invaluable service.

*1. Stirling D, Sherman, M and Strauss S. Thalidomide: A Surprising Recovery. J Am Pharm Assoc. 1997; NS37(3):307-13.*

# From the President

## Make a Resolution for the New Year - Marketing Pharmacy!

Starting the new year is a time for reflection for most of us. We view our accomplishments and failures from the past and make resolutions to change and improve in the future. We often focus on personal agendas such as getting in shape, losing weight or accomplishing a specific goal. I'd like to suggest that you don't forget professional goals in your resolutions for the new year. And among those goals, you should emphasize marketing your profession to others. I strongly believe that marketing our services and contributions to patient care is essential in sensitizing patients, payers, regulators and the public to our value as a profession.

ASHP has responded to a call by its members to conduct an ongoing public relations campaign to promote pharmacy and educate our public on the importance of the health-system pharmacist's role. In the October 1, AJHP editorial, Renee Brehio made a case for promoting National Pharmacy Week all year long. She invites individuals and organizations to contribute together in public relations efforts to "spread the word" about pharmacy to patients, the community and other health care professionals in the following ways:

- Get ASHP's brochures included in your health-system's written orientation material for patients.
- Use the tent card designed by ASHP as a business card to let patients know that you are their pharmacist.
- Get pharmacists included in public events sponsored by your health system, such as health fairs.
- Using ASHP's medication facts sheets, initiate an "Ask Your Pharmacist" column in community newspapers and health-system newsletters.
- Speak to local community groups, civic organization and support groups, and show the slides developed by ASHP.
- Create posters or flyers with positive messages about health-system pharmacy and place them in your health system and in local grocery stores, schools and libraries.

*NCSHP President*
*Steve Novak, MPA*

As an ongoing campaign, ASHP will be promoting the first annual National Health-System Pharmacy Week, Feb. 7-13, 1999. They will be working with NCSHP to make available a variety of materials for promotion to the public:

- camera ready newsletter announcements
- flyers
- tent tray cards
- patient cards
- buttons
- a Power Point presentation
- press materials
- a tip sheet on how to conduct an open house.

ASHP needs to be commended for its provision of materials for a grassroots public relations campaign. In order to have a positive pharmacy public relations impact in society, we all need to take the initiative to actively promote our profession at our own institutions. ASHP has paved the way by providing easy-to-use resources. More information can be obtained by contacting ASHP through their web site, www.ASHP.org, or through the NCSHP office. Everything is ready. What we need to be successful is you. So make the resolution and keep your commitment! Start with National Health-System Pharmacy Week, Feb. 7-13 and market pharmacy in 1999.

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NCSHP Newsletter is a bimonthly publication of the North Carolina Society of Health-System Pharmacists (NCSHP), a non-profit organization dedicated to the enhancement of health-systems pharmacy practice. Subscription to the newsletter is a benefit of membership in NCSHP.

NCSHP members are encouraged to share their views, concerns and ideas with their colleagues by contributing articles to the NCSHP Newsletter. Opinions expressed are those of the author and may not represent the views of NCSHP, its officers, Board of Directors or its membership. Copy deadlines are the 10th of the month prior to the month of the next issue to be published. (i.e. April 10th for the May/June Issue.)

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# Clinical Consultant's Corner

## The New Emphasis on Rural Medicine in Pharmacy

by Bryan Haas, PharmD, MS, Sampson Regional Medical Center

The level of interest the UNC system has shown in rural medicine has increased over the past decade, especially in Sampson County. As part of the continued commitment to rural health, a community based AHEC faculty position was created in 1997 as a split-funded venture by UNC-CH's School of Pharmacy, Southern Regional AHEC, the Duke Endowment and Sampson Regional Medical Center (SRMC). The position was created in order to offer more rural educational opportunities to students since these practice sites prove to be the norm rather than the exception in North Carolina.

Traditionally, rural sites were viewed by health care students and residents as isolated bastions that provided less than standard care. Although this is not an accurate picture of rural medicine, part of the struggle for pharmacists in less populated areas is obtaining access to drug information references. The advent of online drug information, telemedicine and the increase of UNC and ECU faculty members in Sampson County have made health care learning environments a more satisfying venture for students and residents.

Before the introduction of new technology, it was not unusual for pharmacists at SRMC to rely primarily on pharmaceutical company drug information services or AHEC libraries to provide them with information that might be readily available to pharmacists in tertiary health medical centers. Depending on the type and quantity of information requested, the expected turn-around time was several days. Although there is still a significant dependency on these types of services, Internet access and telemedicine are now used as tools to provide quick and reliable drug information to area health care providers.

Integral to the role of educator and clinical consultant has been involvement with the ECU School of Medicine's Rural Residency Program and the Kate B. Reynolds funded PA/FNP Residency Program. The variety of experiences available to students, residents and faculty members through these programs provides a unique experience among rural practice sites.

Several rural clinics are utilized as practice sites for faculty in and around Sampson County. The students are able to actively participate in clinical activities with pharmacists, physician assistants, nurse practitioners and physicians. The community-based faculty position that was created as a result of school and grant money has led to introduction of disease state management clinics, extensive patient counseling, utilization of patient assistance programs, as well as access to drug information services and clinical consult services for both the rural clinics and the local hospital.

In these types of unique practice environments, one must develop a relationship, not only with universities and the AHECs, but most importantly, with local pharmacists and health care providers. They are the individuals who provide the day-to-day care and determine the success or failure of programs. SRMC's department of pharmacy has experienced a great deal of success with increased pharmaceutical ideas, which the staff pharmacists are then able to adapt for use in their own practice. The recent introduction of a heparin nomogram dosed and monitored by pharmacists has resulted in a faster time to therapeutic aPTT. A pharmacist-initiated IV to PO switch program has been used in conjunction with a community acquired pneumonia pathway and resulted in decreased drug costs and shortened hospital stays. Inservices are provided to staff pharmacists on topics that are chosen by the staff.

It is important to have buy-in from local pharmacists and other health care providers. This determines the success or failure of both clinical pharmacy service for rural ambulatory care clinics and hospital monitoring plans in rural plans in rural practice settings. Pharmacists are encouraged to utilize local resources to develop their own unique practices.

# Tech Talk

## Technician Certification: A Step In The Right Direction!

by Darlene Shelton, CPhT
(with Teresa Devora, BA, Greensboro
AHEC Pharmacy)

The role for pharmacy technicians continues to change to meet the changing needs of the health care system. Only a few years ago the technician was a clerk, someone to type labels, stock shelves and answer telephones. In today's health care arena, the pharmacist is spending more time teaching and interacting in patient therapies, therefore, spending less time with routine distribution functions. The pharmacy technician can own the distribution process and provide the pharmacists much needed professional support. If pharmacists ever hope to provide pharmaceutical care to their patients, they will need to give up most of the behind-the-counter distribution process to well-qualified, certified pharmacy technicians.

The national certification offered through the Pharmacy Technician Certification Board (PTCB) is available to help identify and measure the level of pharmacy knowledge technicians bring to the profession. The PTCB examination has provided technicians an avenue for demonstrating their knowledge, gaining respectability and positioning for advanced responsibilities. Technicians passing this national certification examination can use the designation of CPhT (Certified Pharmacy Technician) after their names, identifying them as well-trained health care providers.

Although the process is currently voluntary, the North Carolina Board of Pharmacy is looking at making some form of certification mandatory for technicians. Many employers already actively seek certified technicians to fill vacancies and typically pay 20 percent more salary for this measure of knowledge and dedication to the profession. For example, the Veterans Administration starts technicians at an annual salary of $21,000. In addition, technicians in the VA system have opportunities for taking on more responsibilities and increasing their pay in steps. North Carolina could utilize the PTCB certification process as the initial standard for credentialing technicians in all practice settings. Pharmacists need credentialed technicians in order to step out from behind their counters to provide pharmaceutical care. Pharmacists in all practice settings need time to provide pharmaceutical care to patients. They can find that time by shifting the routine tasks of the distribution process to certified technicians and then sharing liability with technicians by providing liability insurance coverage. The sharing of liability is cost effective and raises the professionalism of technicians. The role of the pharmacy technician will be driven by the need for pharmacists to provide pharmaceutical care. Therefore, a core group of technical personnel to own the distribution process is an important step.

Hospital technicians made up the majority sitting for the PTCB examination initially; however, more and more retail technicians are becoming certified. The majority of the technicians being certified are those who have been practicing for several years. These technicians must be commended for setting the pace for those technicians still deciding on the importance of certification.

If you are interested, there are formalized training programs being offered on multiple levels. The American Association of Pharmacy Technicians (AAPT) can help direct your search but some examples are: 1) self-study guides available through the American Society of Health-System Pharmacists; 2) formal classroom style instruction through the state community college system; 3) fast-paced preparatory courses offered through the North Carolina Area Health Education Centers (AHEC); and 4) continuing education credits to keep your certification current are provided by AAPT and AHEC. Whatever avenue the technician takes to getting certified, he can then go into the work force with proven abilities and feelings of accomplishment. Certification is a step in the right direction.

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*Darlene Shelton is the American Association of Pharmacy Technicians' National Office Manager and the Moses H. Cone Memorial Hospital Narcotic Technician/PYXIS System Manager. She has practiced as a pharmacy technician for 20 years and has witnessed many changes to the profession. She is active in establishing minimum standards and credentialing requirements for pharmacy technicians at both the national and state levels. Darlene has spoken at many national conventions on behalf of pharmacy technicians.*

## Calendar of Events

February 11-12, 1999
**North Carolina Pharmacy Winter Meeting**
Greensboro

March 5-9, 1999
**APhA 146th Annual Convention**
San Antonio, Texas

May 20-23, 1999
**NC Pharmacy Annual Convention**
Atlantic Beach

June 6-10, 1999
**ASHP Annual Meeting**
Reno, Nev.

July 31-August 2, 1999
**ASHP Home Care Meeting**
Chicago, Ill.

September 11-12, 1999
**Pharmacy Practice Seminar**
Wilmington

October 6-7, 1999
**Annual Carolina Seminar**
Greensboro

December 5-9, 1999
**ASHP Midyear Clinical**
Orlando, Fla.

*NCPRN Inc. continued from page 20.*

a favorable working relationship in that they both want to do what is best in order to protect the public. In PRN's case that means early intervention and an appropriate treatment plan for each client which is in his or her best interest as well as that of the public. The Board feels that PRN is an excellent monitoring program for impaired pharmacists, and they work well with Mr. Marley regarding recommendations for the clients. I have been able to attend the Rules Meeting, formal Board meeting and both formal and informal disciplinary hearings held by the Board of Pharmacy during the month of September.

I witnessed the strengthening relationship between the Board and the PRN program when a Memorandum of Understanding between the two organizations was approved. This arrangement will enable impaired pharmacists to enter into a deferred prosecution agreement with NCPRN and the Board, and as a result their names will not be published in the Board's newsletter. This agreement will hopefully encourage impaired pharmacists to seek help from the PRN program while in the early stages of their disease, which will ultimately protect the public from harm, which is the primary goal of both the Board and PRN.

The PRN program is "dedicated to the early identification and intervention of impaired pharmacists and pharmacy students in North Carolina." PRN is also concerned with education. They are organizing several programs and newsletters in the hopes of educating pharmacists, pharmacy students and many other professionals about the disease of addiction. This knowledge will be very beneficial by allowing pharmacists to properly counsel any patients they encounter who are in recovery, and also to help their colleagues who may be exhibiting some warning signs of impairment. Working with the PRN program has been a very educational and rewarding experience in my professional pharmacy training. My hope is that all professionals will become involved in learning about its practice so they can provide the best continuity of care to their patients, and most importantly to "first do no harm." (Hippocrates)

*Election results continued from page 21.*

**Bill Harris, ASHP House Delegate**

William L. Harris, Jr. (Bill), MS, is Supervisor of quality improvement and medication safety at Duke University Medical Center. He received his BS and MS degrees in Pharmacy from UNC. Bill has work experience in patient care services, operations management, drug information, education, ambulatory care, home care and quality improvement.

Bill is currently President-Elect of NCSHP and has served a three-year term on the NCSHP Board of Directors. Bill has been very active in NCSHP committee work; he chaired the Pharmacy Practice Committee and Legal and Regulatory Affairs Committee for two years each. His contributions to NCSHP were recognized in 1993 as the recipient of the Presidential Service Award. Bill represented NCSHP in the ASHP House of Delegates in 1998 and is an active member of ASHP's Grassroots Contract System for legislative issues and programs.

Bill has served as Chair of the Pharmacy Technician Program at Durham Technical College for 10 years and actively provides pharmaceutical care as a volunteer in a community outpatient clinic. He has served on joint legislative committees for NCSHP and NCPhA and served as NCSHP representative on the Board of Pharmacy Practice Act Committee.

**Ballots were counted and certified on Dec. 3, 1998, at the Institute of Pharmacy. A four-member panel conducted the process. All candidates were notified of the results.**

**Fred Eckel, Executive Secretary**

Fred M. Eckel, MS, is a professor at the University of North Carolina in Chapel Hill and Director of the Office of Practice Development and Education. Fred grew up in Philadelphia where he graduated from the Philadelphia College of Pharmacy and Science. It was at the Ohio State University School of Pharmacy and Hospitals where he earned his MS degree and Residency in Hospital Pharmacy. Fred is a pharmacist by choice, commitment and concern. He has worked in community and hospital pharmacy and served as Director of Pharmacy at the UNC Hospitals from 1968 to 1975. He currently serves as Assistant Director for Education and Training there. He is past president of ASHP and NCSHP, and he currently serves as Executive Secretary for NCSHP.

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# Wilkes Regional's Care Connection Pharmacy Helping Those in Need

*Wilkes Regional Medical Center*

Wilkes Regional Medical Center is a 137-bed community hospital located in North Wilkesboro, NC. The towns of Wilkesboro and North Wilkesboro, located in the foothills of the western part of the state, have a combined population of 12,000, and the county has 65,000 citizens.

Three years ago, the medical community identified that there were many people in the community who could not afford their medications and were either not getting their prescriptions filled or were not taking them regularly. Of course, this resulted in increased morbidity and hospital admissions. The hospital, with support from the Duke Endowment and the United Way, opened the Care Connection Pharmacy on the hospital campus to assist those in need.

The Care Connection Pharmacy worked closely with the medical community to develop a formulary of generic and low cost drugs. Patients must qualify through the Department of Social Services, meet food stamp guidelines and not be eligible for Medicaid. The program has met a tremendous need in the community and is a wonderful example of the way the hospital reaches out to the community.

The Care Connection has recently implemented another program titled the Pharmaceutical Manufacturers Assistance Program. Using software and a computer provided by the NC Department of Rural Health, volunteers access the indigent medication programs of the pharmaceutical manufacturers. The volunteers work closely with physicians by completing all the necessary paperwork. Then, the Care Connection pharmacist labels the medications and counsels the patient when the drug arrives.

The pharmacy at Wilkes Regional has been a very active and visible part of the hospital in the past few years. The department has also embraced new technology under Director of Pharmacy, Steve Critz, RPh, a 1972 graduate of the UNC School of Pharmacy. Critz came to Wilkes Regional in 1984 to become director of pharmacy after working as a staff pharmacist for 11 years at Catawba Memorial Hospital in Hickory.

"The pharmacy at that time presented many challenges," Critz said. "And administration recognized it. They promised their support if I would come, and they followed through on their promises. It has been a very rewarding experience."

One of the first things that impressed Critz was the fine medical staff

*Continued on page 28.*

*WRMC Pharmacy Staff: (from left to right) Michael Lamberth, Bob Stipe, Leah Hensley, Catherine Burnhart, Linda Reeves, Gina Key, Melissa Richardson, Renee Shumate and Steve Critz.*

# New Format for NCSHP Awards

This year NCSHP Awards will be given at the NC Pharmacy Annual Convention (formerly the NCPhA Annual Convention) on Thursday, May 20th in Atlantic Beach. Previously, the awards were given at the Winter Meeting in February. Also, note the deadline for nominations is now March 1, 1999. For any additional questions, please contact Tim Giddens, Chair of the Nominations and Award Committee, at 910-671-5176.

Be sure to mark your calendars for the Annual Convention (a joint meeting of NCPhA and NCSHP) on May 20-23 at the Sheraton Ocean Front Hotel in Atlantic Beach. Continuing education programs for hospital, community and consultant pharmacists will be offered at the meeting. There will also be networking opportunities at social functions and a Board Review for students. Please make plans to attend.

## Annual Convention (joint meeting)

## May 20-23, 1999

## Atlantic Beach

*Do you or someone you know deserve special recognition? Would you like to inform other pharmacists and technicians of an activity at your practice site?*

*If so, please send your information to the NCSHP office at:*
*PO Box 968*
*Chapel Hill, NC 27514 or*
*NCSHP@mindspring.com.*

*We rely on our readers to keep us informed of our members' activities. Your help in locating future articles for the NCSHP Newsletter is greatly appreciated!*

*WRMC - Continued from page 27.*

and their eagerness to support new programs and willingness to work with a formulary. The many young physicians on staff had trained at hospitals with formularies and clinical pharmacists. A computer system was installed the following year, monitoring duplications, allergies and drug interactions in addition to the standard IV labels and cart fills. Since the hospital did not have a tube system, a network of fax machines was installed within the hospital to transmit orders and results.

"Back in those days, most people didn't even know what fax machines were, and the real challenge was to get people to understand what they were and how they worked," said Critz. "They really decreased turn around times, but since they were my idea, I somehow ended up doing all the maintenance on them."

The hospital began an $18 million expansion and renovation program in 1987, and in 1990, the pharmacy moved into a brand new department. "I fought hard to make sure the pharmacy was not located in the basement and that we had a window," Critz added.

The pharmacy staff of four pharmacists, four technicians and a clerical assistant take pride in providing comprehensive pharmacy services to the hospital. The department is open until 11 p.m. weeknights and 5 p.m. on weekends. The pharmacy has a rather large chemotherapy program and works with two oncologists that come up from Winston-Salem.

Gina Key, PharmD, is the Clinical Coordinator for the pharmacy. Critz said, "Gina is doing an outstanding job, and I am very proud of the clinical programs we have going. However, I feel all pharmacists are 'clinical pharmacists' and all the pharmacists on staff are capable of providing kinetic consults, drug information or whatever is required. In a small hospital, that's the way it has to be. Of course, we can never forget our primary duty of drug distribution and control. If we can't get the right drug to the right patient in a timely manner, then clinical programs are futile." Critz added, "We have had wonderful technicians on staff that are all certified. I am very proud of them. We could not do all that we do without the support of our technicians."

The pharmacy is also a training site for pharmacy students at UNC and Campbell University. Everyone on staff enjoys having the students on rotation and feels they learn a lot from the students as well. The staff feels small hospitals provide an excellent learning opportunity for students unfamiliar with hospital pharmacy and remember the fear they felt when going into a hospital pharmacy for the first time.

In 1997, the pharmacy began automating the drug distribution within the hospital. Critz said he always felt automation was the way to go, but felt that with all new technology, it would improve and become more reliable and affordable. When he saw a demonstration of the Med Select System by Diebold, Critz said he knew that was the system for which he had been waiting. The nurses love the unit dose dispensing, which requires no counting whatsoever, and the ease of the touch screen to process transactions. The pharmacy is impressed with report-generating capabilities and the amount of paper they are eliminating. Med Select is in place in the Emergency Department and the six nursing stations. They will soon be completing the installation house-wide with the addition of OR, PACU and L&D. This was a great decision for the hospital and the pharmacy, and it is providing great benefits to the patients and staff. Streamlining distribution allows the pharmacists more opportunities for patient involvement.

*Linda Reeves, pharmacy technician, fills Med Select.*

*Care Connection Pharmacy volunteer works beside Pharmacist Lamar Creasman.*

## There's still time...

There is still time to make plans to attend the 1999 Winter Meeting at the Holiday Inn Four Seasons in Greensboro on Feb. 11-12, 1999. There will be on-site registration as space permits. Call the NCSHP office for details.

## Pharmacy Technicians

The PTCB exam will be held:

March 13, 1999
July 10, 1999
Nov. 13, 1999

Applications deadlines are approximately two months prior to the test date.

# Board of Pharmacy

## NCBOP Reports on New Rules

David Work
Executive Director

In October, the members took action on two different rules involving emergency dispensing of prescriptions. One is a modification of the existing rule .1809 which allowed the dispensing of a limited quantity of prescription drugs when the pharmacist is unable to contact the prescriber for refill authorization. Until the Board's action, the limitation was for a 72-hour supply. That was changed to a 30-day supply with a proposed effective date of April 1, 1999.

A different emergency rule attracted media attention which applies to a situation different than that described in the prior paragraph. In situations where a prescriber is unable to provide medical services to the patient, such as the bankruptcy of a medical practice which occurred in Raleigh, the pharmacist may dispense a one-time emergency 90-day supply under certain circumstances. The text of the rule (.1815) is written below and can be found at the Board's web site at *www.ncbop.org* in the New Developments section. Please note that this rule would also apply to a situation where a physician dies unexpectedly or retires.

Ordinarily pharmacists do not want more rules, but nearly everyone agreed that these are good changes and in the public interest.

This Spring elections will occur for two positions on the Board of Pharmacy which will become vacant in 2000. Nominations need to be in the Board office prior to March 10, 1999, with a petition signed by 10 pharmacists from the region they seek to represent. The two positions up for election are the Central District which consists of Mecklenburg, Union, Anson, Richmond and the counties which border them on the north, and the Northeast District which consists of Wake, Durham and Granville counties and those east to the ocean. Specific counties are listed in the Board's rule at NCAC 46.2103. Pharmacists must reside in a county within the district they represent.

Potential candidates should know that Board members are expected to spend at least 50 days per year on Board business away from their regular place of practice. The responsibilities and time demands of the position are substantial, and arrangements need to be made with employers for such service prior to a person seeking election. Ballots will go out by mail in April for return to the Board office and counting in May.

North Carolina is the only state which elects its pharmacist board members, and pharmacists need to prudently exercise this responsibility. This fact is one of the primary reasons for the pioneer action by the Board in certain areas such as the rules specified in this article.

The 1998 session on the General Assembly adjourned without approving the registration of technicians by the Board. Leaders at the North Carolina Pharmaceutical Association have expressed the opinion that the elections in November of 1998 produced a climate more receptive to pharmacy issues. If you wish to be active in such matters, you should contact Dan Garrett at NCPhA at 1-800-852-7343.

### .1815 Emergency Prescription Refill Due to Interruption of Medical Services

In the event a pharmacist or device and medical equipment permit holder receives a request for a prescription refill and the pharmacist is unable to obtain readily refill authorization from the prescriber because of the prescriber's inability to provide medical services to the patient, the pharmacist or permit holder may dispense a one-time emergency supply of up to 90 days of the prescribed medication, provided that:

1.) The prescription is not for a Schedule II controlled substance;
2.) The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition;
3.) In the pharmacist's or permit holder's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences;
4.) The dispensing pharmacist or permit holder creates a written order entered in the pharmacy's automated data processing system containing all of the prescription information required by Section .2300 of these Rules and signs that order;
5.) The dispensing pharmacist or permit holder notifies, or makes a good faith attempt to notify, the prescriber or the prescriber's office of the emergency dispensing within 72 hours after such dispensing.

History Note: Authority G.S. 90-85.6; 90-85.32; Filed as a Temporary Amendment Eff. Oct. 29, 1998. (A temporary rule is effective for 9 months from the date it becomes effective.)

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# Patient Counseling: Chronic Cancer Pain; Part 2

Thomas A. Gossel, RPh, PhD
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Vol. XVI No. 6

**Goals.** The goals of this lesson are to discuss chronic cancer pain, and present information useful in counseling patients and their caregivers about how to manage this condition.

**Objectives.** At the conclusion of this lesson, successful participants should be able to:

1. differentiate between characteristics of various types of pain;
2. select from a list those components that distinguish the chronic pain syndrome from other forms of pain;
3. exhibit knowledge of the drug treatment options for chronic cancer pain;
4. show an understanding of the pharmacologic actions and adverse effects associated with drugs used to treat chronic cancer pain;
5. demonstrate knowledge on how to counsel patients and their caregivers on how best to control chronic cancer pain.

*Provided As a Service to the Profession Through an Educational Grant-in-aid from*

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This is Part 2 of a two-part lesson series. Part 1 discussed chronic pain and its treatment with opioids. Part 2 continues the topic, and also discusses the use of adjuvant drugs and non-drug treatments of chronic cancer pain. It ends by presenting information for counseling patients and/or their caregivers on treatment of chronic cancer pain.

## Factors that Influence Opioid Pharmacokinetics

**Age.** Increased age can decrease renal clearance of morphine enhancing its accumulation and increasing serum levels. Geriatric patients may also experience greater sensitivity of central receptors to morphine compared to their younger counterparts. Doses should be reduced or intervals between doses lengthened to minimize development of serious adverse effects in these individuals.

**Cirrhosis** alters absorption and elimination of meperidine, pentazocine, and propoxyphene, but not morphine, resulting in their accumulation. Since renal excretion is a major route of elimination of active drug metabolites, opioid elimination is decreased in patients with **renal failure**. This results in drug accumulation with increased possibility of toxicity.

Some **tricyclic antidepressants** may increase the bioavail-ability and half-life of morphine in cancer patients. Concurrent administration of drugs that induce the hepatic mixed-function oxidase (Cytochrome P450) system can alter the metabolism of certain opioids. By a yet unknown mechanism, severe allergic reactions including excitation, abnormally high fever, convulsions and death have been reported after administration of meperidine to patients treated with a monoamine oxidase inhibitor.

**Adverse Effects to Opioids.** Adverse effects to opioids are diverse, the intensity of response varying with the particular drug. The most common adverse effects include nausea and vomiting, constipation, drowsiness, sedation, confusion, dizziness, euphoria or dysphoria, hallucinations, and miosis. In general, tolerance develops to most side effects (except constipation) in 24 to 48 hours.

**Nausea and Vomiting.** Opioid analgesics induce nausea and vomiting by an action on the medullary chemoreceptor trigger zone. These symptoms can be the major reason for a person refusing to accept the large doses of opioids necessary for pain relief. Giving an antiemetic concurrently with the opioid, or initiating treatment parenterally, then switching to the oral route, may effectively prevent nausea and vomiting.

**Constipation.** Constipation can be expected with all opioids. It is often reported to be the most uncomfortable response to opioid therapy. Opioids act at multiple sites within the GI tract and spinal cord to reduce intestinal secretions and peristalsis.

Constipation can be prevented with the use of dietary fiber, increased fluid intake and/or daily use of a stool softener with or without a mild stimulant laxative (e.g., bisacodyl, standardized senna concentrate). One of the goals of therapy is to maintain normal bowel movements so that the patient does not have additional concern about constipation.

**Euphoria and Sedation.** Some persons with chronic cancer pain desire the euphoria associated with these drugs. It generally diminishes within three to five days. Persistent drug-induced sedation should be reported to the patient's physician. Sedation may signify that the dose of analgesic is excessive and should be reduced.

**Biliary Spasm and Urinary Retention.** Opioids increase smooth muscle tone to induce bladder spasm in some patients. In others, they increase sphincter tone leading to urinary retention. Persons with pathologies of these organ systems, especially the elderly, should be observed carefully when receiving opioids.

**Seizures.** Chronic dosing with meperidine is associated with seizures. Seizures result from accumulation of an active hepatic metabolite, normeperidine. Accumulation is enhanced when renal function is impaired. Normeperidine lowers the seizure threshold to cause tremors, multifocal myoclonus (muscle spasm and twitching) and seizures. Seizures should be controlled by discontinuing meperidine. They are not reversed with naloxone.

**Respiratory Depression.** This is the most potentially serious adverse effect of opioid therapy. Although clinically significant, respiratory depression is not normally a problem with oral therapy. Opioids act on brainstem respiratory centers as a function of dose to increase respiratory depression to the point of difficult breathing. All opioids produce similar levels of respiratory depression at equianalgesic doses.

**Physical Dependence.** Physical dependence, unlike psychologic dependence, is characterized by development of the abstinence syndrome upon abrupt drug withdrawal or administration of an opioid antagonist. This is noted by agitation, lacrimation, frequent sneezing, yawning, tremors and insomnia, all of which are symptoms of sympathetic nervous system hyperexcitability. Short-acting opioids usually cause more intense withdrawal than the longer acting agents.

**Tolerance.** Tolerance is a predictable outcome of chronic opioid therapy and develops in nearly all patients. In a tolerant individual, a larger dose of medication or increased frequency of administration is required to maintain analgesia. Tolerance for various effects develops at different rates. It occurs quickly to sedation, and also appears more rapidly to intravenous or continuous infusion dosing of opioids than to doses given by patient-controlled analgesia (PCA). Many cancer patients do not develop tolerance to opioids until further along into therapy, and can remain on the same dose of medication for prolonged periods of time.

**Psychologic Dependence.** Psychologic dependence ("addiction") describes a person's craving for and hoarding of the drug, and overwhelming desire to procure it. The threat of psychologic dependence is reportedly the primary barrier to obtaining optimal pain control. Psychologic dependence is not a true pharmacologic property of opioid drugs. Instead, it is a psychologic and behavioral syndrome. Part of the misunderstanding of psychologic dependence by healthcare providers is that, while tolerance and physical dependence occur and are expected, only rarely does the former condition develop in cancer patients who were not dependent previously on opioids. Still, fear that it will occur is reported to be a primary reason why these patients often receive subtherapeutic doses.

A study of nearly 12,000 cancer patients who received one or more doses of opioids revealed that only four developed psychologic dependence. The need to increase the dose of an opioid is usually indicative of tolerance, or escalation of the disease process, rather than psychologic dependence to the drug.

**Other Adverse Effects.** Dry mouth, urinary retention, itching, myoclonus, altered cognitive function, dysphoria, euphoria, sleep disturbances, sexual dysfunction, physiologic dependence, tolerance, and inappropriate secretion of antidiuretic hormone have been reported as adverse effects to the various opioids.

Table 1 summarizes opioid analgesics.

## Adjuvants to Opioid Therapy

Anxiety, depression, and other symptoms often accompany pain. Attempts to control pain alone may be futile unless these other symptoms are also addressed. Adjuvant drugs are valuable during all phases of pain management to enhance analgesic efficacy of opioids synergistically, treat concurrent symptoms, and provide independent analgesia for specific types of pain.

**Tricyclic Antidepressants.** Tricyclic antidepressants produce direct analgesia and potentiate morphine analgesia. They are useful in neuropathic pain such as from nerve damage caused by surgery, chemotherapy, or nerve infiltration. The drugs are particularly useful in patients with depression and insomnia concurrent with pain.

The most widely reported experience for the use of tricyclic antidepressants in treating chronic cancer pain has been with amitriptyline. Its side effects of urinary retention, dry mouth, and delirium may be intolerable for some patients. Nortriptyline, its active metabolite, reportedly causes less anticholinergic action and sedation. It has been employed in patients who could not tolerate amitriptyline.

**Corticosteroids.** These drugs elicit a broad range of effects including anti-inflammatory activity, antiemetic activity, mood elevation, and appetite stimulation. They may be useful in the management of cachexia (generalized ill health with emaciation) and loss of appetite. Corticosteroids also reduce cerebral and spinal cord edema and are essential in emergency management of elevated intracranial pressure and epidural spinal cord compression. They are effective in treating severe bone or visceral pain.

**Anxiolytics.** Promethazine and hydroxyzine are mild anxiolytics with analgesic, sedative, and antiemetic properties. When combined with morphine, they cause additive analgesia, and are suited for cancer patients with anxiety.

Benzodiazepines are useful anxiolytics, but do not have established definite analgesic properties. An exception may be alprazolam that appears to confer analgesia in cancer patients with phantom limb pain.

**Anticonvulsants.** These are used to manage neuropathic pain, especially stabbing or burning pain since they suppress spontaneous neuronal firing. In cancer patients undergoing therapy with bone marrow suppressants, such as chemotherapy and radiation treatment, anticonvulsants should be used only with a great deal of caution since they can cause idiosyncratic or dose-related bone marrow suppression.

**Acetaminophen, Aspirin and Nonsteroidal Anti-inflammatory Drugs.** These drugs are useful adjuvants to opioids in chronic cancer pain because of their independent actions and synergistic activity. They may be useful as sole therapy when cancer pain is described as mild (WHO Step 1). They are also used in combination with opioids in more severe pain (WHO Steps 2 and 3). The WHO (World Health Organization) analgesic ladder was described in the first article in this series.

These drugs differ from opioids in several important ways. They reduce fever and have an anti-inflammatory effect. They do not produce physical dependence or tolerance. However, they have a ceiling effect above which increased doses do not provide additional relief.

## Table 1
## Representative Opioid Analgesics Used in the Treatment of Cancer Pain

| Agent | Dosage Form | Trade Name |
|---|---|---|
| Opioid Agonists | | |
| Codeine | injection, tablet | N/A |
| w/Acetaminophen | capsule | |
| | tablet | Tylenol w/Codeine |
| | oral liquid | Tylenol w/Codeine |
| | tablet | Empirin w/Codeine |
| Fentanyl | transdermal patch | Duragesic |
| Hydrocodone | N/A | |
| w/Acetaminophen | capsule | Lorcet, Vicodin |
| w/Aspirin | tablet | Lortab |
| Hydromorphone | injection, tablet, suppository | Dilaudid |
| Meperidine | injection, tablet, syrup | Demerol |
| Morphine | injection | Astramorph, Duramorph |
| | SR capsule | Kadian |
| | tablet | MSIR |
| | CR tablet | MS Contin, Roxanol SR |
| | SR tablet | Oramorph SR |
| | oral liquid | MSIR, OMS, Roxanol |
| | suppository | RMS, Roxanol |
| Opium & Belladonna | suppositories | B&O Suppositories |
| Oxycodone | CR tablet | OxyContin |
| | CR tablet | Roxicodone |
| w/Acetaminophen | capsule | Roxilot, Tylox |
| | tablet | Percocet |
| | oral liquid | Roxicet |
| w/Aspirin | tablet | Percodan, Roxiprin |
| Propoxyphene | capsule | Darvon |
| w/Acetaminophen | tablet | Darvocet N |
| Mixed Agonists-Antagonists | | |
| Butorphanol | injection | Stadol |
| | nasal spray | Stadol NS |
| Pentazocine | injection | Talwin |
| | tablet (w/Naloxone) | Talwin NX |
| w/Acetaminophen | tablet | Talacen |
| w/Aspirin | tablet | Talwin Compound |

### Auxiliary Modalities for Controlling Pain

**Cutaneous Stimulation.** There are a number of noninvasive means to help control pain. These include application of heat, cold, pressure, massage, vibration and electrical stimulation.

**Exercise.** Useful in treating subacute and chronic pain, exercise strengthens weak muscles, mobilizes stiff joints, helps restore coordination and balance, enhances patient comfort, and provides cardiovascular conditioning. During acute pain, exercise should be limited to self-administered range-of-motion. Weightbearing exercise should be avoided when bone fracture is likely.

**Repositioning.** Immobilized patients should be moved frequently to maintain correct body alignment and prevent or alleviate pain. This will also limit pressure ulcer formation.

**Counterstimulation.** Transcutaneous Electrical Nerve Stimulation (TENS) is controlled, low-voltage electrical stimulation applied to large myelinated peripheral nerve fibers via cutaneous electrodes. Patients with mild pain may benefit from a trial of TENS to see if it is effective in reducing the pain.

Pain may be treated with acupuncture. Because pain can signal disease progression, infection or treatment complication, patients who choose acupuncture should be encouraged to report new pain problems to their health care provider.

**Cognitive-Behavioral Interventions.** Interventions are an important component of a multi-modal approach to pain management. They help the patient develop a sense of control as well as coping skills to deal with pain. When introduced early in the course of illness, patients are more likely to succeed because the interventions can be learned and practiced while the patients have sufficient strength and energy. Patients should be encouraged to try several techniques such as listening to music, and focusing attention on things other than pain. Praying or making self-statements such as, "I can cope," or listening to someone read are examples. The patient's family can be very helpful in providing conversation and activities that will distract the patient from concentrating on pain.

### Counseling Patients and Their Caregivers on Chronic Cancer Pain

Patients who suffer chronic pain should be encouraged to speak frankly about their pain. They should be motivated to verbalize their pain in exacting terms, and try to distinguish between pain from other symptoms such as depression. They should describe each pain separately to ensure that the unique qualities of each type are recognized and treated properly.

They should be made to feel that chronic cancer pain is not a sign of weakness. They should be encouraged to never feel that they are "bothering" their physician and caregivers when they talk about their pain or request additional medication.

Cancer patients and their caregivers should also realize that when doses of medication are increased to achieve successful analgesia, they are developing tolerance to the drug, not becoming addicted to it.

One of the challenges in working with chronic pain patients may be in dealing with the stigma that is often placed on them. It is not solely the lay community that misunderstands chronic pain and long-term opioid use.

Patients may be under-compliant due to their fear of addiction. Health professionals — physicians, nurses, pharmacists, and others — frequently assess patients on opioids in that manner. It is not uncommon to identify patients who are under-treated for pain because their physician worries about adverse drug effects, development of tolerance, or turning a patient into an addict. Or, a physician may be concerned about personal liability and/or legal ramifications of prescribing controlled substances. Statistics show that a chronic pain patient who has no previous addiction history is at low risk for becoming addicted to opioids.

It is the physician's ethical duty to help the patient by relieving pain. This supports increasing doses, even at the risk of adverse effects. Because many patients with cancer pain become opioid tolerant during long-term therapy, the clinician's fear of shortening life by increasing opioid doses is usually unfounded. Nurses and pharmacists should not be stumbling blocks to providing proper pain relief to patients with cancer.

Above all else, cancer patients desire dignity. Health care providers, caregivers, and family members must respect their right to comfort. Pain should be controlled. Dignity and self-esteem will be maximized when pain is minimized. The quality of life for the rest of the patient's life will be enhanced when pain is minimized.

*Happy New Year!*

*From your NCPhA and NCSHP Staff*

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# Continuing Education Quiz

## Patient Counseling: Chronic Cancer Pain; Part 2

1. Among the factors that influence opioid pharmacokinetics, cirrhosis is LEAST likely to alter the absorption and elimination of:
   a. meperidine.
   b. morphine.
   c. pentazocine.
   d. propoxyphene.

2. In general, tolerance develops to side effects of opioids with the EXCEPTION of:
   a. sedation.
   b. miosis.
   c. drowsiness.
   d. constipation.

3. Which of the following is the LEAST appropriate treatment for opioid-induced constipation?
   a. Fiber
   b. Drinking lots of fluids
   c. Saline cathartics
   d. Stool softeners

4. Opioid drug dependence that is characterized by development of an abstinence syndrome upon abrupt drug withdrawal or administration of an opioid antagonist describes:
   a. physical dependence.
   b. psychologic dependence.

5. Opioid dependence that is characterized by a person's craving for and hoarding of an opioid drug and the overwhelming desire to procure it describes:
   a. physical dependence.
   b. psychologic dependence.

6. The need to increase the dose of an opioid to maintain pain relief is LEAST likely to be an indication of:
   a. the development of tolerance.
   b. escalation of the disease process.
   c. psychologic dependence to the drug.

7. The group of drugs used adjunctive to opiates to potentiate analgesia sufficient enough to be useful in treating neuropathic pain is the:
   a. calcium channel blockers.
   b. nonsteroidal anti-inflammatory drugs.
   c. phenothiazines.
   d. tricyclic antidepressants.

8. The group of drugs used adjunctive to opiates to manage neuropathic pain because they suppress spontaneous neuronal firing is the:
   a. anticonvulsants.
   b. antihistamines.
   c. antipsychotics.
   d. anticholinergics.

9. The group of drugs used adjunctive to opioids to provide antiemetic activity, mood elevation and appetite stimulation is the:
   a. amphetamines.
   b. benzodiazepines.
   c. anorectics.
   d. corticosteroids.

10. All of the following opioids are commercially available in combination with acetaminophen and/or aspirin EXCEPT:
   a. hydrocodone.
   b. oxycodone.
   c. hydromorphone.
   d. codeine.

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# Small Doses

## NCPhA Elects President for 2000 and Three New Board Members

•**Randy Ball** was elected to serve as President-elect for NCPhA in 1999 and become president in 2000. **Henry Herring, Gray Stewart** and **Davie Waggett** will join the NCPhA Executive Committee in 1999, replacing outgoing Committee members **Constance McKenzie, Joseph Moose** and **William Morris**. The new officers will be installed at the Annual Convention in May.

• NCSHP intern and UNC Pharmacy School student **Macary Weck** was elected as the APhA Region III Delegate at the Midyear Regional Meeting in Memphis, TN. Region III covers seven states and Puerto Rico and includes fourteen pharmacy schools.

• **Cathy Fuquay** of Kernersville was selected by the American Society of Consultant Pharmacists to participate in the ASCP Research and Education Foundation's Alzheimer's/Dementia Traineeship for Consultant Pharmacists.

• **Geraldine Anastasio**, PharmD, from Charlotte, was recognized as a Fellow of the American College of Clinical Pharmacy. The fellowship is awarded to ACCP members who have demonstrated a sustained level of excellence in clinical pharmacy practice or research.

• Ed and **Linda Shelburne**, RPh, were featured in the September 1998 issue of *Medicap News Capsule* for their exceptional Medicap Pharmacy in Whiteville.

• **John Andrews**, owner of Andrews Pharmacy in Winston-Salem was presented with the Eagle Award by the Professional Compounding Center of America Inc., a provider of technical training, bulk pharmaceuticals and devices for independent community pharmacists.

# Letters to the Editor

**Dear CJP,**

Congratulations with the supplement to *Pharmacy Times*. It presents the project very well and is a significant addition to the pharmaceutical care literature: a super project!

Best Regards,
Bram Hartzema, PharmD, MSPH, PhD
Professor, Schools of Pharmacy and Public Health
Director, Center for Pharmaceutical Outcomes Research
UNC-CH

**Dear CJP,**

I regret very much that I will be unable to attend the Joint Meetings (for unification). I was able to attend the last meeting of the Legislative Committee, at which time I expressed my strong support of the proposed One Voice-One Vision unification.

I have been a member of the Association for 52 years, and I cannot remember when the profession has been less effective when it comes to legislation or standing in the health profession.

Let's have One Voice, but have committees of each specialty in pharmacy within the Association. Let their voice be heard whenever they have a special interest, but first work out the problems within the Association and then go to the Legislature or Congress unified. Today, I do not think we can get any bills passed being as divided as we are. We should respect all pharmacists of each specialty, but let us solve our problems within the Association, not out fighting with each other.

I love my profession, and I dislike seeing it so divided that we are ineffective in our efforts to improve.

I hope my opinions are not taken to be against any individual, but taken from someone who wants to see our profession move to greater heights.

Sincerely,
John T. Henley
Clinic Pharmacy (retired)
Hope Mills, NC

**Dear CJP,**

In appreciation for the interest free loans I received while I was in school, I would like to make a contribution to the Consolidated Pharmacy Loan Fund.

Sincerely,
Emily K. Severt
Clemmons, NC

SPOTTED: The letterhead of Lowry Drug Co. in Statesville reads, "Lowry Drug Co. Inc.— Where Pharmacy is a Profession." CJP couldn't have said it better.

QUOTE FOR THE DAY: "There is a time in the life of every problem when it is big enough to see, yet small enough to solve." — Mike Leavitt

# 1998 Recipients of the "Bowl of Hygeia" Award

Wyeth-Ayerst Laboratories takes great pride in continuing the "Bowl of Hygeia" Award Program developed by the A. H. Robins Company to recognize pharmacists across the nation for outstanding service to their communities. Selected through their respective professional pharmacy associations, each of these dedicated individuals has made uniquely personal contributions to a strong, healthy community which richly deserves both congratulations and our thanks for their high example.

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# North Carolina Pharmaceutical Association

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*Please complete and/or make corrections to section 1-3 and return with payment in the enclosed envelope to*
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| **Professional Degree** | | **NC License Number** | | | |
| **College of Pharmacy** | | **Year Graduated** | | | |

**Employment Information** ☐ *Same as above*

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Roan Mountain at the NC/Tennessee border is beautiful anytime of the year. The views are magnificent. In the Springtime, the branches are lush with branch lettuce, and you may even catch a speckled trout in the streams if you are a good fisherman. This is the home of the Rhododendron Festival and the Rhododendron Gardens. The hills are covered with pink blooms in June as far as the eye can see. In the Fall, the air is crisp, even cold. The Appalachian Trail runs through here. Anytime, any season, there are hikers with overnight backpacks to travel on foot further up to the mountain meadows. The moon is bigger and brighter, and even God seems closer. The Winter is quiet. I grew up here and have wonderful memories of sledding down the hills and through the curves. Now there are many cross-country skiers who enjoy the serene beauty. Enjoy beautiful Roan Mountain anytime!

~ Sandy Depew ~

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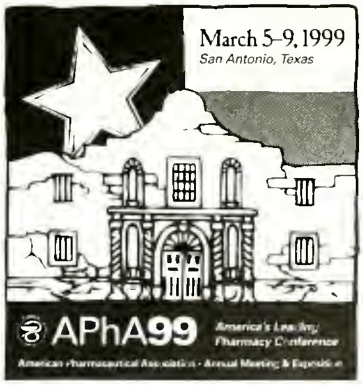
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with NCSHP Newsletter

Volume 79, Number 2

MARCH/APRIL 1999

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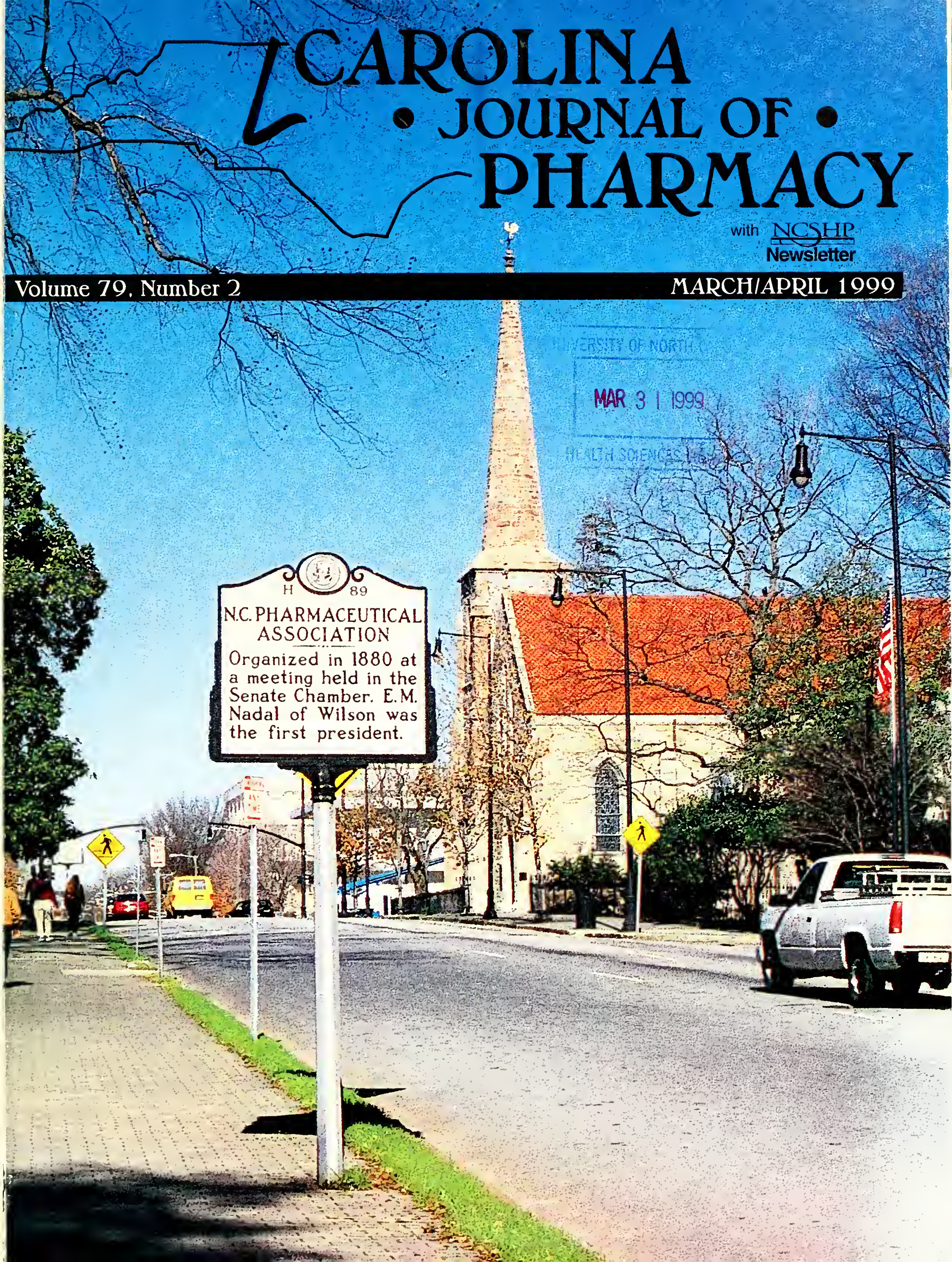
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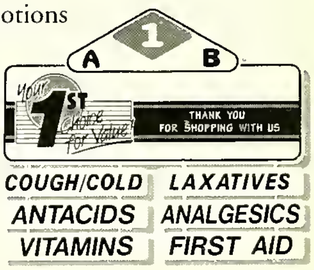

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# CAROLINA
# • JOURNAL OF •
# PHARMACY

## Cover

*The NC Pharmaceutical Association's historical marker in front of the State Capitol Building in Raleigh. Photo by Jennifer Olivia Windley.*

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# Voice and Vision

Daniel G. Garrett
Executive Director

## *"The Elected Listen to People Who Vote"*

The most powerful political party is the one with the votes. Voters have the unique privilege of deciding who gets elected and who is voted out of office. Legislators and elected officials pay attention when a potential voter contacts them. I have been told that pharmacy issues do not get attention because there is not a compelling public outcry for our causes. I agree with this assessment. Many pharmacists are too busy, not informed or are apathetic on legal and regulatory matters. Lack of interest by pharmacists leads to low awareness of our issues by the public. People can't support or vote for causes they don't know about. The weakest political parties are those with the fewest votes.

We must transform pharmacy from a position of political weakness to a respected profession that can help shape public policy.

The starting point on this journey is the education of our profession on the political landscape and land mines. This issue of the journal outlines the current political issues for pharmacy on both the state and national level. We offer suggestions for interaction in our political and regulatory system. The issues seem redundant, complimentary, contrary and controversial all at the same time. Complexity is the biggest challenge we face. We cannot explain issues to the public and legislators that we don't understand or can't put in simple terms.

Unity of voice is the next step toward political strength for pharmacy. The major impetus for the merger of pharmacy organizations is the need to have professional clarity and focus on public policy issues. Different pharmacy factions have competed and disagreed in the legislature resulting in confusion and failure to pass any pharmacy initiatives. We must recognize the diversity of opinions within pharmacy and resolve our differences before we publicly debate our positions. We must be like the proverbial Italian family that fights like cats and dogs among themselves, yet stands as one, protecting each other in public.

The final step on the path to political strength is to have patients talk directly to their legislators. Notice I said patients. We must frame our issues around benefits to patients. Legislators are constantly assailed by special interest groups and lobbyists. The best way to get the attention of a representative or senator is to have a voter from their hometown contact them and present the issue from a personal perspective.

The Legislative and Regulatory Task Force is taking action to support three bill proposals in this year's legislative session:

1) Universal Prescription Card — All health care benefit providers will be responsible for providing a universal health care identification card in the format approved by the National Council for Prescription Drug Programs. This would expedite claims processing and ensure patient confidentiality. Patients benefit by having a standard card to reduce confusion and frustration with prescription claims processing. Chain pharmacy is champion for this proposal.

2) Bill 866 as proposed in 1998 — This bill is being reintroduced by Sen. Tony Rand. The premise of this bill is that patients will be allowed to get their prescriptions filled at any pharmacy if they are willing to pay the difference between their third party co-pay and the pharmacy's customary fee for filling prescriptions. Patients benefit by increased access to prescriptions and by being able to choose to maintain their relationship with their preferred pharmacist. The Retail Pharmacists' Association is lobbying for this bill.

3) Physician-Directed Drug Therapy Management — The North Carolina Association of Pharmacists is working with the Medical Society to develop a bill proposal to legislatively authorize collaborative practice agreements between physicians and pharmacists. Patients in many health care settings currently benefit from collaborative practice protocols, and this bill would provide the framework for expanding drug therapy management to more people in community settings. All four state pharmacy organizations have contributed to contracting with a leading lobbyist to get this bill passed.

We are optimistic about getting all three bills passed. Pharmacists have contacted their representatives and senators, and we have worked hard to build alliances with other health care providers. The key to success will be convincing the legislature of positive impact of these initiatives on the voting public. I ask each of you to inform the patients you care for and suggest that they contact their representative to let them know of their support for improved pharmacy services. When the voters speak, the elected listen.

## ~ Public Notice ~

On Feb. 10, 1999, the North Carolina Pharmaceutical Association filed documents at the Orange County Courthouse to legally do business as the North Carolina Association of Pharmacists. Please note our name change on future mailings and publications. Thank you.

## APhA

## Priorities and Outlook for the 106th Congress

APhA's highest priority in this Congress is to expand upon the opportunities available for recognition of and reimbursement for pharmacists providing pharmaceutical care services and to remove legislative and regulatory barriers which block this progression. Issues such as managed care reform, confidentiality, a Medicare drug benefit and improving end-of-life care are at the top of the list of items to be discussed. Each of these issues has tremendous potential to impact the profession in all areas of practice.

**Medicare Drug Benefit:** Last year, Congress convened a bipartisan task force of representatives, senators and outside experts to work on solutions to the Medicare program's financial woes. This Commission is charged with providing Congress by March 1, 1999, with recommendations for reforming the program. One idea discussed by the Commission and endorsed by the President during his State of the Union Address would expand the Medicare program to include a prescription drug benefit. However, the high cost associated with providing prescription medications is a big hurdle for the Commission and Congress to navigate.

APhA supports Medicare coverage of prescription drugs, provided that the benefit is implemented well and is accompanied by reimbursement for drug therapy management services. However, this will be a tough fight for the profession. Congress and the Commission are trying to come up with a solution to the high cost of medications and have not yet addressed whether or how to pay for drug therapy management services. It will be up to the profession to show that a drug benefit, when accompanied by drug therapy management services, will actually save money in the overall health care system.

**Medicare Diabetes Self-Management Benefit:** APhA and a number of other health care organizations are carefully watching the Health Care Financing Administration's (HCFA) implementation of the Medicare Diabetes Self-Management Benefit. As most pharmacists are aware, HCFA chose to implement the benefit in two phases —the first of which did not include pharmacists as eligible providers of the diabetes education benefit. APhA has commented to HCFA on the Agency's implementation and will be ready to approach members of Congress for their help should HCFA's second implementation phase fail to recognize qualified pharmacists and pharmacies as eligible educators and providers.

**Improving End-of-Life Care:** APhA and a coalition of other health care organizations are taking the lead, with Sen. Ron Wyden (D-OR), to develop legislation to improve end-of-life care. End-of-life care, including pain management, is an area needing significant attention for regulatory reform, payment incentives and improvements in education for patients, physicians, pharmacists and other health care professionals.

**Confidentiality of Patient Medical Records:** Congress is under a statutory deadline of August 1999 to develop legislation which addresses concerns related to the confidentiality of patient medical records. APhA's key points in this debate are 1) pharmacists must be included in any discussion of confidentiality, 2) pharmacists must have access to patient medical information, 3) administrative burdens must be minimal and 4) there should be a separation between the data needed by health care providers, researchers and payers.

**Managed Care Reform:** Managed care reform and the "patients' bill of rights" have already seen some action. Both the Republicans and the Democrats have introduced their own versions of Patients' Bill of Rights legislation. Rep. Charlie Norwood (R-GA) has introduced H.R. 216, the Access to Quality Care Act (AQCA), his successor to the Patient Access to Responsible Care Act (PARCA). Each of these bills addresses issues such as access to emergency care, patients' rights to appeal medical coverage decisions and banning gag clauses in provider contracts.

---

## ASCP

## Advocating Pharmacists in Senior Care

**Medicare PPS for SNFs: Prescription Disaster:** ASCP is advocating for changes to the current Medicare prospective payment system (PPS) for skilled nursing facilities (SNFs) because it restricts Medicare beneficiaries' access to needed and appropriate medications. ASCP will continue to educate Congress and Health Care Financing Administration officials about the problems with PPS and propose solutions.

**Ensuring Access to SNF Care under PPS:** Anecdotal evidence collected from ASCP members shows that residents are being denied access to SNF care because of expensive medication regimens. These anecdotes have proved successful in demonstrating the flaws of PPS to Congress.

**Medicare Prescription Drug Benefit:** ASCP is proactively advocating for legislative proposals to implement a Medicare prescription drug benefit. In January, ASCP members laid the foundation for these efforts by lobbying Congress.

**Protecting Pharmacists' Access to Patient Information:** In 1998, ASCP influenced changes to legislation restricting access to patient information by educating members of Congress on the role of consultant pharmacists in patient care. ASCP will continue to advocate for enactment of pharmacy friendly legislation in 1999.

**DEA:** ASCP continues work with the DEA to achieve a solution to the problems associated with disposal of controlled substances from long-term care facilities.

**State Priority Issues**

**Pharmacy Services in Assisted Living:** ASCP's proactive lobbying efforts will seek to increase the number of states adopting provisions in ASCP's Model State Language for pharmacy services in assisted living facilities.

**Restrictions on Transmissions of Prescription Information:** ASCP will advocate for national legislative provisions as states attempt to restrict transmissions of patient prescription drug information and restrict pharmacists' access to patient information.

**Board of Pharmacy Composition:** In 1999, states will consider revising board of pharmacy composition. At the urging of ASCP, many states will consider requiring that a long-term care pharmacist be included as a member.

**Collaborative Practice:** In 1998, ASCP members testified in support of proposals to implement collaborative practice agreements. ASCP will continue to advance these proposals in the states through aggressive proactive lobbying initiatives and presentation of testimony.

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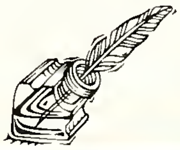

### by Mike James, RPh

Year after year, the Gallup poll shows pharmacists to be the most trusted professionals in the United States. Pharmacists should be proud of this honor and understand its true meaning. Because of this trusted position, hundreds of patrons enter community pharmacies every day to ask pharmacists' advice on everything from their medication to the color they are painting their house.

Yet, despite pharmacists' personal involvement with their community, they are not adequately informing legislators of the vital issues facing pharmacy. These elected officials could make a vast difference in how pharmacy is now practiced today and in the future. National and state associations of pharmacy are working daily to inform legislators about problems affecting our profession, and they need your help.

## Your Voice is Important

The thousands of pharmacists across the nation should become aware that their opinions are important to these elected officials. One constructive way to exert a positive influence is to speak with your legislator when he or she comes into your pharmacy. Many pharmacists have elected officials who are patrons who visit their pharmacies on a regular basis. These visits give you the opportunity to discuss your questions and concerns with them as they ask your opinion and judgment about their medications. Pharmacists should seize this opportunity to discuss pertinent legislative matters affecting pharmacy. Another way is to visit legislators in their office after making an appointment.

## Pleasant Surprise

You will be pleasantly surprised by the positive reaction of these legislators as you explain and discuss pharmacy matters. In many cases, they have not had the opportunity to discuss with a practicing pharmacist the ramifications of pending legislation. So it is imperative to approach legislative patrons and keep them informed of such pharmacy legislation.

Pharmacy has faced difficult issues over the years, but it seems as if it is now facing some of its most trying challenges. Pharmacists should understand these challenges and let their voices be heard. If we do not work diligently together to preserve our profession, the future practice of pharmacy may not be recognizable as we know it today.

We all know pharmacists who mistakenly take the attitude, "There is nothing I can do to affect legislation." We should be willing to speak up and help these pharmacists understand the many ways they can be a positive factor in the legislative process.

## Get Involved

The North Carolina Association of Pharmacists is involved in the legislative process. If you as a pharmacist are not currently involved in the state association's activities, you should make every effort to become associated with the legislative committee and assist with its programs. Through this support, the state association can get more people involved on a one-to-one basis. This broadens the committee's power when the legislature is in the session.

## Pharmacists' Obligation

Everybody likes to be appreciated. A complimentary "thank-you" letter is long remembered when a legislator has supported your legislation. Similarly, express your displeasure, in a positive and professional manner, when the reverse happens. Legislators need to know they are being watched by the voters - their constituents. It is the obligation of pharmacists to step forward and participate in molding the future of pharmacy.

## Pharmacy Issues in the 1999 N.C. Legislature

The 1999 Long Session of the General Assembly convened on Jan. 27, 1999. Sen. Marc Basnight was elected President Pro Tempore of the Senate, and Rep. Jim Black was elected Speaker of the House. The Democrats are in the majority in the Senate with 35 Democrats and 15 Republicans. The Democrats are in the majority in the House with 66 Democrats and 54 Republicans. This is the first time the Chambers have not been split since 1993.

The General Assembly will face difficult problems as the session gears up due to a shortfall in revenue. The current estimate comes in around $800 million. This is due to tax cuts legislated in the 1997-98 session as well as law suits lost during the same period of time. The challenge at hand will be to balance the budget, overcome the shortfall and initiate new programs deemed necessary by the majority of legislators. All of this while addressing hundreds of new bills that will be introduced prior to May of 1999.

Pharmacy has important legislation to be considered during the 1999 session. Several issues will be addressed including the Practice Act Revision, Prescription Drug/Competition, Uniform Prescription Drug Cards and others. I am sure there will be legislation introduced by others that will affect pharmacy either intentionally or unintentionally, and this legislation will have to be addressed. With Sen. Basnight and Rep. Black pledging to end the session by July 1, bills will have to move quickly and efficiently or they will be dropped at cross-over day in May. It is extremely important that all members of the Association find out who their Senate and House representatives are in the General Assembly. You will be asked to contact your representative and urge him/her to support pharmacy legislation during the 1999 Session. You are the pharmacist; you are the expert. No one in the General Assembly knows more about your profession than you. Use this opportunity to educate your Senate or House member in the complexity of pharmacy. Information will be forwarded to you as bill numbers are assigned. Do your very best ... Pharmacy is counting on you.

# Leveling the Board —

by Charles D. Reed, Pharmacist,
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## A Guide to the Process that All Pharmacists Need to Know

Every day, it seems that someone, somewhere is working on something having to do with administrative rules governing or affecting the practice of pharmacy or the business of pharmacy. While credit for many of these rules is appropriately given to the North Carolina Board of Pharmacy, other state agencies, boards and commissions are active players in the same arena. However, regardless of the agency involved in the rule-making process, a statutory procedure is in place to assure the orderly adoption of appropriate rules and to allow public access and participation in the proceedings. The more pharmacists understand the process, the better prepared they should be to promote and defend their professional interests and concerns.

North Carolina's rule-making activity is governed by General Statute (G.S.) 150B, the Administrative Procedure Act. According to G.S. 150B-2(8a), a rule is defined as " . . . any agency regulation, standard or statement of general applicability that implements or interprets an enactment of the General Assembly or Congress or a regulation adopted by a federal agency or that describes the procedure or practice requirements of an agency. The term includes the establishment of a fee and the amendment or repeal of a prior rule. . ." Among other things, G.S. 150B-19 prohibits adoption of a rule unless the agency is authorized by law to adopt such a rule, i. e., the agency must have appropriate statutory authority. Also prohibited are rules that enlarge the scope of a profession or occupation for which an occupational license is required.

The administrative procedures process requires agencies to give public notice of rule-making activities in the North Carolina Register which is published twice a month. It provides opportunities for public comment to agencies about their rules proposals. It provides for individuals to petition an agency to adopt a rule. It provides for the development of fiscal notes to determine the economic impact of a rule. It provides checks and balances against inappropriate and overzealous regulation through day-to-day oversight by the Rules Review Commission, an agency that has the authority to accept or reject proposed rules. It provides for legislative review by the North Carolina General Assembly, and under certain circumstances, it provides for administrative hearings and judicial review by the courts. (A copy of the Administrative Procedures Act may be obtained via the internet at *http://www.ncga.state.nc.us/html/1997/statutes/toc.html*). Concerning the North Carolina Board of Pharmacy, pharmacists need to remember that the Board's statutory responsibility is to protect the public health, safety and welfare in accordance with the specific limited authority granted to it by the North Carolina General Assembly.

The protection and promotion of the profession of pharmacy is the responsibility of pharmacists, not the Board. Therefore, when the Board's proposals are in conflict with the best interests of the profession or may result in unintended potential or actual harm to the public we serve, it is the responsibility of pharmacists to step forward, either individually or collectively, and make their case in a well-reasoned, persuasive and effective manner. The administrative procedures process assures pharmacists the opportunity to effectively voice their concerns about proposed rules, as well as their support.

It is important for pharmacists to understand that the Board of Pharmacy does not have absolute authority over things that affect the profession. In matters affecting the practice of pharmacy in hospitals and nursing homes, actions of the Medical Care Commission may have equal weight or may take precedence; the Social Services Commission may adopt rules affecting pharmacy practice in jails; and the Board of Agriculture may adopt rules governing the packaging and labeling of medications. The actions of the North Carolina Medical Board, the North Carolina Board of Nursing, the North Carolina Drug Commission and the North Carolina Insurance Commission may all affect the practice of pharmacy.

It is also important for pharmacists to understand that no matter how well-intended, or good, or great a proposed rule may be, unless it is considered in the appropriate forum, it is destined to fail. Attempts to circumvent the legislative process with rule making will be derailed by the Rules Review Commission. Attempts to place into effect a rule that is contrary to the public policy of the state will likely be quashed by the General Assembly.

Critical to the continued success and progress of the profession in North Carolina is the interest, understanding and participation of each pharmacist in the adminstrative processes that many times define our profession and how we practice it. Collectively, and in a coordinated fashion, we can usually be more effective than individually. Building bridges and partnering with others outside pharmacy who share common concerns can often be very effective. Also critical to the continued success and progress of the profession in North Carolina is a professional organization that efficiently monitors the administrative processes; fully informs, educates and communicates with pharmacists about the issues and their many facets; and effectively coordinates, represents and advocates the best interests of the profession.

North Carolina pharmacists have almost limitless access to the administrative tools of government. It is the pharmacists' responsibility to use these tools to their best advantage.

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# What Are the Standards? The Question of Pharmacist Certification

It is difficult to read a pharmacy journal today without the mention of the words "pharmacist credentialing", "certificate programs" and "reimbursement." But where are we, the pharmacists of North Carolina, in the process of credentialing? To date, there has been no national consensus on what certificate program is necessary for reimbursement for pharmaceutical disease state management. While certificate programs are not new to pharmacy, the standardization of those programs with reimbursement as the endpoint is new.

It has long been felt that for North Carolina pharmacists to receive reimbursement for disease-state management services there must be some statewide, standardized credentialing program. This program should be acceptable and recognizable to other health care professionals and to health care payers. Standardized credentialing would assure interested parties and patients that the pharmacist is qualified to provide and perform such health care services. North Carolina now has a standardized credentialing program in place.

The North Carolina Center for Pharmaceutical Care (NCCPC), along with the Pharmacy AHEC Program, has taken a leadership role in the standardization of certificate programs for pharmacists. NCCPC established a certificate program review committee (CPRC) in conjunction with the deans of the two Schools of Pharmacy that is responsible for establishing standards and granting approval for certificate programs.

Various programs have been offered throughout the state since 1997, all approved by the CPRC. Since that date, there have been 18 programs offered which cover six topics, including diabetes management, anticoagulation, preventative cardiology, women's health, asthma management and smoking cessation. Approximately 25 pharmacists have participated in each program.

The guidelines from NCCPC state programs must have minimum competencies, be academically rigorous and curriculum based. Self-study, classroom and clinical sessions, examinations, and development of a pharmaceutical care implementation plan are all requirements and must total a minimum of 28 hours. Each participant must complete three cases (including patient work-up and monitoring plan) during the didactic portion of the program and provide an additional three cases from their practice site. There is no time limit set by NCCPC for the completion of each program although individual programs may set a limit. At this time, approximately 60 percent of the program participants have been certified.

Even with the NCCPC standards, several issues are yet to be resolved. For example, there is currently no system to address the transfer of credentials when pharmacists relocate within the state or from one state to another. The certificate program may fulfill the criteria, yet can still differ from region to region within the state. A previously established program illustrates the point. The Greensboro AHEC (GAHEC) program has conducted five certificate programs and has certified approximately 100 pharmacists. The Greensboro group approached credentialing in another manner. A group of pharmacists asked area physicians to set the standards for their certification programs thus assuring that referring physicians were comfortable with the pharmacists' expertise. The criteria are more stringent than standards set by NCCPC and include the write-up of 12 patient cases, group discussion of 40 cases and a minimum of 33 hours. Therefore, a pharmacist certified in asthma management from GAHEC would meet and exceed the NCCPC criteria. However, if the pharmacist's certificate were from an NCCPC approved program, he/she would not meet the GAHEC standards and would not qualify for their referral list.

Recently, another group began offering competency assessment in our state. The National Association of Boards of Pharmacy (NABP) is offering disease state management examinations in diabetes, asthma, dyslipidemia and anticoagulation. This offering is administered by the North Carolina Board of Pharmacy and states that it is a credentialing examination. However, this is an examination only and does not require the completion of a certificate program. This program does not meet the NCCPC or the GAHEC standards.

One has to ask what is being done in other states and nationally since this issue is not unique to North Carolina. One state that has taken a stand is Tennessee. Since 1995, the University of Tennessee-Memphis has administered a three-day program that meets all the NCCPC criteria and also includes a session on reimbursement. The program granted certificates to 200 pharmacists in the first year. The program is now available via videotape while the University provides on-site instructors to maintain the interactive nature.

On a national level, the American College of Apothecaries offers a program on pulmonary disease management that is even more demanding. Additionally, the upcoming American Thoracic Society/American Lung Association meeting in April has an agenda item to consider the development of certified asthma educators similar to the program administered by the American Diabetes Foundation. These programs apply to the certification of all health professionals and include, but are not limited to, pharmacists.

The North Carolina Association of Pharmacists (NCAP) Education Task Force is recommending that a universally accepted statewide standard for certificate programs be developed. Also, they recommend that standard disease state management certificate programs be offered across North Carolina through the AHEC system so that a well-distributed group of pharmacists can be trained.

While each of the programs offers some advantages, the need for a standardized method of certification is obviously needed to allow pharmacists to progress to a level that will build confidence in our abilities to both physicians, who will refer patients to pharmacists' care, and to patients who expect expert care. However, many significant questions need to be addressed before standardization can succeed.

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Special thanks to Steve Caiola for his assistance with the content and editing of this manuscript.

# Practice Profile

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**Describe your overall practice.**
Medical Center Pharmacy is a clinic-based pharmacy that opened in 1990 in conjunction with the formation of a new comprehensive family practice/internal medicine facility, the New Hanover Medical Group. The primary purpose for the formation of this pharmacy was to provide convenient pharmaceutical services for those patients served by the medical group, as well as continuity of care by enhancing communication among physicians, nurses, pharmacists, etc. The patient population is primarily adult and elderly from the southeastern counties of North Carolina. In 1992, a large pediatric practice, the Children's Clinic, approached us about the possibility of opening a small clinic pharmacy in their nearby building to meet the pharmaceutical needs of those families with sick children. The pharmacy was opened in a converted examination room near the checkout.

**What is unique about the patient services you provide?**
Because of our close proximity to the physicians' offices at both locations and the degree of interaction that we have with these doctors and their staff, we were able to more easily evaluate the needs of patients and physicians' practices that might benefit from additional pharmaceutical services. We provide respiratory services (i.e. home oxygen, nebulizer therapy, CPAP and BIPAP) in conjunction with our respiratory therapist and asthma management services through our pharmacist staff. We began providing diabetes management services to patients by referral from physicians after one of our pharmacists, Beverly Clark, attended specialized training in this area. She is currently Board Eligible to become a Certified Diabetes Educator. Compounding has become an increasingly interesting portion of our practice with concentration on sterile and transcutaneous preparations. Women's health issues that include natural hormone replacement is a new area of cognitive services that we are focusing on.

*Diabetes Specialist, pharmacist Beverly Clark, provides counseling to a patient referred from a physician's office.*

*Pharmacist Henry Herring prepares a sterile dosage form in a laminar airflow hood.*

**How did you determine the need for this service? How did you develop your practice to meet that need?**
One way that we have determined need is through physicians and/or their staff calling to ask if we know anything about a subject, following up on their requests and sharing new ideas for services with them. Marketing of existing services and programs is important in maintaining growth.

**Are you being reimbursed for the services you provide?**
We currently charge for diabetes management, asthma management and women's health consultations. We do not try to bill insurance, so patients pay for the services they receive, and a receipt is provided to them to file with their insurance if they choose.

**What lessons have you learned as a result of this experience?**
We have learned that any additional service that you provide costs in training, implementation and energy. To begin any new service, you must determine if you have the proper staff to maintain a particular program, and if the staff has the desire to meet that new challenge. Not all programs will be equally successful based on need and timing. Our physical facilities are limited, and this has been an obstacle. But the self-satisfaction that it has provided professionally has been rewarding for all members of our pharmacy staff. I don't feel that we should attempt to provide all types of cognitive services, but we should determine what works best at our practice site and support other pharmacies as they develop their own programs.

**What were your stumbling blocks?**
The two biggest stumbling blocks for our extended services has been our lack of space (I joke that I can never be accused of under utilizing square footage) and secondly, my procrastination to market our services (although my background before opening my first store was in sales with Eli Lilly and Co.) I think one of my strengths has been my ability to hire and maintain a staff that wants to see our business grow and be innovative and to invest in training and education that provides them with increased responsibility and personal/professional growth.

**Where are you heading now with your practice?**
I will be moving my home medical equipment business (Medical Center Home Care) and my rehab company (Medical Center Rehab Technologies) to a new facility near New Hanover Regional Hospital in March 1999. Later this year in that facility, we plan to open a compounding pharmacy with additional space for cognitive services.

# Chain Drug Store Management Links Up to Discuss Hot Topics

by Jimmy Jackson, VP of Pharmacy Relations, Eckerd Corp.

Members of management from Eckerd Corp., CVS, Kmart, Wal-Mart, Kroger and Kerr Drug met together on Jan. 12, 1999, at the Institute of Pharmacy, to discuss emerging issues in chain pharmacy across the state. It was the first delegation of its kind on the state level.

The morning started with introductory remarks by Dan Garrett, executive director of NCAP, who captured everyone's attention when he explained that he was not an advocate for, nor had any intention of, forming a pharmacy union. Then he explained how the Association was attempting to combine all disciplines of pharmacy in North Carolina into a single organization, and he stressed the need for chain drug pharmacists to be involved.

Chain pharmacists make up almost 50 percent of local pharmacy association membership, yet participation is very limited. Gender factors, limited time for attendance, convenience and travel time were just a few of the possible reasons listed. It was speculated that most pharmacists attend the local meetings to obtain continuing education hours. After small group discussions, a poll was taken that showed the group's most important goal is to get more chain pharmacists involved in the Association.

Other important topics were also discussed at the day-long meeting. Dr. David Work informed the group that the NCBOP inspectors would be increasing their surveillance practices at chain pharmacies this year. Dr. Work also distributed a Board of Pharmacy analysis of the pharmacy work force in North Carolina, which indicated that there are more pharmacists available per site than at any other time in recent history. The chain operation personnel had difficulty with the BOP's numbers, and commented that despite what the report revealed, there is a shortage of pharmacists to hire.

Jimmy Jackson commented to Dr. Work on the NACDS study that predicted that in five years the number of prescriptions would increase 44 percent while the number of pharmacists would remain constant. Jackson also pointed out that 38 states are presently reporting shortages of pharmacists and that the shortage is now conservatively estimated at approximately 3,500 pharmacists.

A discussion also developed around 12-hour days and the Board's policy on lunch breaks, which was recently overturned by the Rules Review Commission. Chain management uniformly commented that 12-hour days were the results of individual pharmacists' choice, not chain management scheduling.

In the afternoon, the delegates were divided into groups to prioritize goals for the respective problems affecting chain pharmacy. Once the lists were posted, each one was given the opportunity to vote for those items that he/she deemed most important. The three receiving the most votes were 1. Getting chain pharmacists involved in the Association, 2. Chain pharmacist representation on the BOP, and 3. Coming up with a standardized electronically readable drug card. These were followed closely by passing the Collaborative Practice Act legislation.

All attendees agreed to continue the dialog, and a date for a follow-up meeting was chosen. It became readily apparent that chain pharmacy wants to be a participant in the new pharmacy organization, and that the mechanism for the involvement is through the local pharmacy associations.

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## NCPA

### Bipartisan Proposals for the 106th Congress

John M. Rector, General Counsel

The 35,000 pharmacies and the 75,000 pharmacists that the National Community Pharmacists Association (formerly NARD) represents are interested in a wide range of health and business issues such as state tax reform, government competition, managed care accountability, Medicare reform, confidentiality of pharmacy records and the Patients' Bill of Rights. Currently, NCPA is focused on the following bipartisan proposals:

- The Quality Health Care Coalition Act, introduced by Rep. Tom Campbell, which will provide antitrust exemption to health care professionals engaged in negotiations with managed care entities. (See H.R. 4277 - 105th Congress.)
- The Prescription Drug Benefit Equity Act, presented by Rep. Nita Lowey, to assure that Americans, including federal employees and retirees, are not discriminated against by insurance contracts that force them to leave their local pharmacists for a mail order company. (See H.R. 1525 - 105th Congress.)

Additionally, NCPA supports all steps necessary to stop the FDA from implementing its Dec. 1, 1998, Medguide Patent Labeling Rule which was prohibited by Congress in 1996. (See PL104-180 & 601.)

# Focus on Regulatory Changes for Success

In North Carolina and across the country, community pharmacy faces the growing challenge of promoting regulatory change and modernization. This article, presented by the National Association of Chain Drug stores (NACDS), highlights the most prominent of these challenges in North Carolina and nationally that must be addressed as we approach the 21st Century.

### Pharmacy Manpower

Community pharmacy is suffering an acute shortage of pharmacists, which threatens to intensify. The volume of community pharmacy prescriptions in the United States is projected to surpass 4 billion in 2005, up from 2.7 billion in 1998. In North Carolina, our projections show an increase in prescription volume of 50 percent by the year 2005 compared to 1998, but a decrease in number of pharmacists. The result is that if current trends persist, the average number of prescriptions that a pharmacist in North Carolina will be required to dispense in an 8-hour shift will increase by over 50 percent between now and 2005.

NACDS and its member companies strongly support regulatory policies that advance a pharmacist's role in patient care. However, in order to do so in an era of pharmacist shortages, we believe state Boards of Pharmacy should reform state Pharmacy Practice Acts and allow pharmacies to use all the technology at their disposal to increase dispensing efficiencies. Pharmacies should be encouraged to use pharmacist technicians to perform non-judgmental tasks, freeing the pharmacist to spend more time counseling patients.

### Error Prevention and Prescription Accuracy

A North Carolina rule assumes dispensing errors result from excessive pharmacist workload, which the Board has defined by policy as 150 prescriptions per pharmacist shift. NACDS does not agree with arbitrarily selecting a set number of prescriptions per day to determine the safety of a pharmacy. Depending on many factors, such as the staffing and training levels in a given pharmacy, its use of technology and its commitment to systematic procedures and quality control, a pharmacist in one pharmacy may not be able to safely fill many more.

The marketplace demands that pharmacies safely and efficiently dispense prescriptions. Pharmacies have developed internal quality assurance programs to make sure that safety is not sacrificed as new methods of efficient dispensing are implemented. However, in the context of the pharmacist shortages, we believe that regulations or policies that arbitrarily link dispensing errors to prescription volume without any scientific proof are counterproductive and illogical.

### Pharmacist Workload

As the public's most accessible health professional, pharmacists have traditionally found it difficult to find breaks in their busy days. In recent years, certain circumstances such as pharmacist staffing shortages, increasing prescription volumes and difficulties with insurance claims transmissions, have made breaks increasingly difficult to schedule.

While NACDS believes that pharmacists should have meal and periodic rest breaks, requiring breaks of specific duration at times when patients may need immediate attention or when the pharmacy is extremely busy will increase errors and stress. NACDS believes pharmacists should use professional judgement in taking breaks and not be required to use a "punch-the-clock" approach.

### Advancing the Pharmacist's Role in Patient Care

As important as the dispensing function is, chain pharmacies realize that providing patient-oriented care is a key element in the future of pharmacy. Therefore, NACDS supports regulations that enable pharmacists to focus on disease-state management and other "cognitive" services. Areas of patient care of special importance include:

**Pharmacist credentialing.** The National Institute for Standards in Pharmacists Credentialing (NISPC) was jointly established in June 1998 by NACDS, the National Association of Boards of Pharmacy (NABP) and the National Community Pharmacists Association (NCPA). The Institute's activities represent a coordinated approach to create national standards for examinations to credential pharmacists in specific disease states and serve to establish a basis that third-party payers may use to reimburse pharmacies for these patient-care services.

**Medicaid payment for pharmacy services.** Mississippi Medicaid now recognizes the value of pharmacy services and reimburses pharmacies for disease state management performed by pharmacists who meet credentials established by the state Board of Pharmacy. Chain pharmacy supports this program and others that recognize these valuable pharmacy services.

**Medicare payment for diabetes self-management programs.** Medicare now covers diabetes self-management education for patients with diabetes in an outpatient setting. NACDS has been working, along with several other national pharmacy groups, to ensure that Medicare will recognize pharmacy-based programs for this service. NACDS supports all efforts to include community pharmacy in this important benefit.

**The Asheville Project.** NACDS appreciates the work of the North Carolina Center for Pharmaceutical Care and the positive result from the Asheville Project. This innovative program demonstrates the value of the interaction between pharmacists and patients to improve lives and save payers money.

Pharmacy manpower and regulations inhibiting the effective use of pharmacy staff top the list of pertinent community pharmacy issues for NACDS. In an era when the demand for prescription drugs will grow far faster than the supply of pharmacists, ensuring that pharmacies can implement dispensing efficiencies remains our primary regulatory goal.

NACDS is working toward a better profession for pharmacists and patients in North Carolina and nationwide. To succeed we must find innovative ways to meet the crisis in prescription volume and manpower shortages, maintain patient safety, improve outcomes and increase patient satisfaction. NACDS will work cooperatively with state boards, pharmacists and consumers to build a better pharmacy system for the years to come.

## Materia Medica

# Zyban® (bupropion hydrochloride) for Smoking Cessation

by Chris Sugg, PharmD Candidate, UNC School of Pharmacy

Approximately 50 million people or 25 percent of the population smoke in the United States. Closer to home, North Carolina ranks as the tenth highest state in the percentage of adults who smoke. In 1997, almost 30 percent of men and 23 percent of women were smokers in North Carolina. While the percentage of smokers has decreased, recent data suggest an increase in teenage smokers. The economic consequences of smoking in direct medical costs is estimated at $50 billion dollars a year and $47 billion dollars in total indirect costs. This habit kills more than 400,000 people each year in the United States which translates to one out of every five deaths.

Several FDA-approved treatments have been marketed to help individuals kick the habit, yet only one provides a clear alternative to nicotine. Zyban®, manufactured by Glaxo Wellcome, is the first non-nicotine agent for smoking cessation that offers smokers an entirely new way to quit smoking. Zyban® was cleared for marketing by the U.S. Food and Drug Administration on May 14, 1997, and is indicated as an aid to smoking cessation treatment. The active ingredient of Zyban® (bupropion) was initially developed and marketed as an antidepressant. While the activity of bupropion is unrelated to tricyclic, tetracyclic, SSRIs or other known antidepressant agents, it does have weak inhibitory properties on the neuronal uptake of norepinephrine, serotonin and dopamine. The mechanism to which Zyban® enhances the ability of patients to abstain from smoking is unknown; however, it is presumed that this action is mediated by noradrenergic and/or dopaminergic mechanisms which have been implicated as pathways of nicotine addiction.

The effectiveness of Zyban® as an aid to smoking cessation was demonstrated in two placebo-controlled, double blind studies. Over 1,500 chronic smokers who smoked at least 15 cigarettes a day participated. In one study, Zyban® was compared to placebo; in the second study, Zyban® was evaluated versus placebo, a nicotine patch and in combination with the patch. In both studies, all patients received brief smoking cessation counseling.

The first study was a dose response trial, in which patients were treated for seven weeks with one of three doses of Zyban® (100 mg, 150 mg or 300 mg/day) versus placebo. The primary outcome was total abstinence during the last four weeks of treatment (weeks 4 through 7). Abstinence was verified by objective carbon monoxide levels in expired air and subjective patient dairies.

Results of the dose response trial revealed continuous abstinence increased with an increasing dose of Zyban®. This was significantly more effective than placebo at the 300mg/day dose.

The pivotal trials demonstrate that Zyban® is an effective non-nicotine medication for smoking cessation. It demonstrates efficacy over placebo and may provide an added benefit for patients who want to quit smoking when used in combination with the nicotine patch. Zyban® is well-tolerated, and the most common side effects associated with its use are dry mouth and insomnia. Health Care Providers should be made aware that Zyban® does have the same active ingredient in Wellbutrin® and is contraindicated in patients with a seizure disorder due to the risk of a dose-dependent seizure. In doses of 300mg/day or less, the seizure rate is approximately 0.1 percent (1/1000) with extended release bupropion like that used in Zyban®. This incidence was determined during an 8-week treatment exposure in approximately 3,100 patients. It is currently recommended for reducing the risk of seizure that Zyban® should be initiated at 150 mg/day for the first three days, then increased to 150 mg BID for a total daily dose of 300mg/day. Treatment with Zyban® should begin while the patient is still smoking, since approximately one week of treatment is required to achieve adequate steady-state blood levels of bupropion. Doses should be at an interval of at least eight hours between successive doses. To avoid the main side effect of insomnia, a good recommendation is to schedule the afternoon dose no later than 4 p.m. Therapy should continue for seven to 12 weeks unless risks outweigh benefits of therapy. If the patient has not made significant progress by the seventh week while receiving counseling and behavioral support, it is unlikely he or she will quit during that attempt, and treatment can be discontinued.

A cost analysis of other smoking cessation agents shows that Zyban® may be a cost-effective recommendation. Based on the lowest duration of treatment (seven weeks), Zyban® may cost approximately $135. Other prescription smoking cessation therapies may cost approximately $247 dollars for Nicotrol NS, $157 for ProStep and $224 for Habitrol. OTC smoking cessation therapies may cost approximately $228 dollars for Nicoderm CQ, $228 for Nicorette gum and $135 for Nicotrol.

This is good news for patients who want a cost comparable, effective, oral non-nicotine therapy for smoking cessation. Zyban® provides easy twice-daily oral dosing over the potentially embarrassing and awkward nasal spray delivery of Nicotrol NS. Zyban® is the first non-nicotine therapy that addresses the biology of addiction by acting presumably on the dopaminergic pathway, not as a replacement therapy like that of the other prescription or non-prescription agents. And with concomitant use with the patch, clinical trials demonstrate higher abstinence rates that may increase the success of cessation.

For further information on addiction or the use of Zyban®, you can contact Glaxo Wellcome or visit their web site at *http://www.glaxowellcome.com.*

*References:*

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# Get a grip…

## on NC Pharmacy Issues at the

# 1999 NC Pharmacy Annual Meeting & Convention

May 20-22, 1999
Atlantic Beach Sheraton
Atlantic Beach, NC

## Preliminary Schedule

THURSDAY — May 20, 1999

◊ Registration
◊ Educational Workshops (2 of 4)
- Teaching Diabetic Patients to Use Their Medication and Their Equipment and Supplies (e.g. gizmos)
- Teaching Asthmatic Patients to Use Their Medications and Their Equipment and Supplies (e.g. gizmos)
- Herbal and Nurticeutrical Products - What Do We Tell Our Patients?
- Reimbursements for Pharmaceutical Care in the Inpatient, Ambulatory Patient and Long-Term Care Patient Settings

◊ Board Exam Review for New Graduates (at Holiday Inn)
◊ Awards Presentation
◊ Exhibits and Reception for Awardees
◊ Shag Dance

FRIDAY — May 21, 1999

◊ Continental Breakfast & Exhibits
◊ Business Meeting
◊ Educational Session
- Pharmaceutical Care for the Patient with Osteoporosis
- New Medications for Arthritis

◊ Board Exam Review (con't)
◊ Exhibits and Lunch
◊ Auxiliary Business Meeting
◊ Free Time
- Golf and Tennis Tournaments
- Beach time on your own

◊ Pool side Cookout

SATURDAY — May 22, 1999

◊ Continental Breakfast
◊ Business Meeting
◊ Educational Sessions
- Protecting the Skin from the Sun and What to Do When It's Too Late!
- Pharmaceutical Care for Antiplatelet/Anticoagulation Patients

◊ Auxiliary Luncheon & Officer Installation
◊ Technician C.E. Program
◊ Free Time
◊ Fort Macon Tour (conducted by NCPhA member and Docent Emil Cekada)

◊◊ Child Care and Children's Activites are being planned. ◊◊

Look for registration information coming soon in the mail! Make plans to attend now!

NORTH CAROLINA SOCIETY OF HEALTH-SYSTEM
NCSHP
PHARMACISTS
Newsletter

Volume 22, Number 2 The bimonthly publication of the North Carolina Society of Health-System Pharmacists March/April 1999

# First Combined Winter Meeting Fulfilling for NC Pharmacists in all Practice Settings

by Macary Weck
UNC PharmD Candidate

On Feb. 11-12, 1999, the pharmacists in the state of North Carolina witnessed a landmark event — the first ever *combined* pharmacy meeting. The North Carolina Pharmaceutical Association (NCPhA), the North Carolina Society of Health-System Pharmacists (NCSHP), the North Carolina Chapter of the American Society of Consultant Pharmacists (NCASCP) and the North Carolina Retail Pharmacy Association (NCRPA) have decided to unify and create a pharmacy organization which will represent the pharmacists in this state with "one voice and one vision." This joint effort towards unification will bring pharmacists all over North Carolina closer together and reduce the fragmentation that can occur with separate pharmacy organizations.

The new state organization, the North Carolina Association of Pharmacists (NCAP), strives to represent the needs of all its members, regardless of what environment they practice in. This vision was evident with the array of speakers and educational programming present at the NC Pharmacy Winter Meeting.

The program began with a keynote address from John Gans, executive vice president of the American Pharmaceutical Association (APhA). His talk entitled "Creating Unity for Action" was inspiring as he spoke about pharmacy from the national view. He discussed a number of "hot topics" relating to pharmacists and the provision of pharmaceutical care. He mentioned a number of groups of people who will be critical for pharmacists to collaborate with to assure the safe provision of health care. His talk encouraged pharmacists to work together to fight the enemy — disease.

Next, Chris Decker, executive vice president of the Pharmacy Society of Wisconsin (PSW), spoke about the unification experience in his state. His reflections on the problems they encountered and how PSW dealt with them was insightful for our state. There is no doubt that we will encounter similar challenges and successes and can anticipate these now due to this discussion.

After a brief break, Dan Garrett from NCAP spoke about where our state stands in the One Voice One Vision process. The floor was then opened up for questions from the audience, which were addressed by representatives from each of the four organizations participating in the unification. This "Town Hall Meeting" allowed both the officers and the members to dis-

*Meeting continued on page 26.*

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# ASHP Issues in 1999

by Brian M. Meyer, Director, Government Affairs Division, American Society of Health-System Pharmacists

The American Society of Health-System Pharmacists' top advocacy issues include improving the safe use of our nation's drug supply, adequate fund raising for pharmacy residencies through federal and state programs, confidentiality of patient information, reimbursement for pharmacists' services and a prescription drug benefit for Medicare beneficiaries.

Recent Congressional attention has focused on the perceived increase in the number of drugs withdrawn from the market as well as the product safety precautions that are required by the Food and Drug Administration. Critics contend that increased approvals resulting from the Food and Drug Administration Modernization Act of 1997 led to the increased number of drug withdrawals and safety warnings. ASHP has always been a leader in improving the medication use process to help patients make the best use of their drug therapy. ASHP's expertise was recently recognized by an invitation to appear at a conference sponsored by the General Accounting Office (GAO) to discuss drug safety issues. ASHP Executive Vice President and CEO Henri R. Mannasse Jr., PhD, ScD, provided the practitioner's perspective on the current postmarketing surveillance system. ASHP plans to work closely with members of Congress, the GAO and the FDA to improve adverse drug event reporting and postmarketing surveillance.

Preserving and increasing funding for pharmacy residencies is another important government affairs initiative. Graduate medical education (GME)

*ASHP continued on page 27.*

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# *From the President*

## Building for the Future

NCSHP President
*William L. Harris*

Many changes in the last few years have affected how we practice — technological advances in distribution, computer enhancements, robotics and drug information resources via the Internet. Yet the need for pharmacists continues to grow. Our ability to adjust to health care changes will prevent us from being a victim and allow us to continue to serve our patients.

Starting about two years ago, pharmacy leaders in North Carolina began discussing the wisdom of working together more closely to strengthen our pharmacists and the profession as a whole to remain an integral part of the health care team. Many said that pharmacists are too divided by workplace, practice type, location, affiliation and other factors. But these differences can also be our strength if we work together with common goals.

Leaders of the pharmacy professional organizations in North Carolina (NCSHP, NCPhA, NCRPA and NCASCP) have committed themselves to unite our professional talents into one pharmacy organization that will enhance our skills, keep our vision on our patients and fulfill our role in serving the public. Numerous articles, meetings and programs have discussed this plan. Many NCSHP members have served on the eight task forces developing the foundation of the new organization. It has been a positive experience, and there is need for more members to participate and support these endeavors.

At the Winter Meeting, Bruce Canaday, president of ASHP, commented that building relationships is key to creating the future of pharmacy. We must plan with the end goals in mind and develop common standards across practice settings. John Gans, executive vice president of APhA, commented that our common enemy is disease, not each other. Unity creates strength for action.

NCSHP's professional goals are accomplished through active participation in committee activities. Major themes of this year's Annual Implementation Plan are communication, unity and collaboration with others to promote pharmacy and deliver pharmaceutical care to our patients. The following list of committees, strategic charges and leaders will assist you in understanding important activities for this year. Committees with corresponding unification task forces will accomplish their goals through the task forces.

◊ Mike Soucie will chair the Program Committee (Education Task Force) which will plan joint CE meetings with the other organizations to enhance drug therapy management skills.

◊ Beth Williams and Regina Schomberg will co-chair the Membership Committee (Membership Task Force) to foster the mentorship program, enhance member benefits and increase pharmacist, student and technician membership.

◊ Mark Ninno will chair the Communication and Public Relations Committee (Marketing and Communications Task Force) to improve communication with members through development of a world class web site with expanded links and interactive programming.

◊ Ken Burleson will chair the Legal and Regulatory Affairs Committee (Legal and Regulatory Task Force) to coordinate professional efforts to pass legislation that enables collaboration with physicians in drug therapy management and monitor other legislation.

◊ Chris Lehman will chair the Administrative SIG (Professional Relations Task Force) which will build and strengthen professional relations with physicians, nurses, industry and allied health care groups.

◊ Karen Petros and April Cooper will co-chair the Pharmacotherapy SIG to increase pharmaceutical care activities, assist members in skill development and share successes with members.

◊ Chris Jones will chair the Pharmacy Practice Committee to enhance pharmacy practice, initiate or enhance residency programs and coordinate mini-rotations to increase drug therapy management skills.

◊ Alice Faust and Laurie McElhone will co-chair the Pharmacy Technician Committee to enhance educational materials and CE meetings and increase membership to develop participation in the professional organization.

Student leaders from the Schools of Pharmacy at UNC and Campbell University will co-chair the Pharmacy Student Committee to place students on each of the above committees to help the committees meet student needs and develop future pharmacy leaders.

These committees and task forces are creating the future of pharmacy in North Carolina. If you would like to participate in these activities, notify the committee chair or me for more information. Join us in building relationships that will focus on the needs of our patients and prepare our pharmacists for the future.

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## Distinguished Lecturers to speak at UNC School of Pharmacy

This Spring, the UNC School of Pharmacy continues to host a number of events geared toward the professional and intellectual development of its students. In addition to regular classroom instruction, these kinds of programs offer unique learning opportunities for students and members of the community alike.

The School's Annual Career Day took place on Feb. 5 and was a great success. The purpose of the event was to introduce students to the wide range of employment opportunities available to pharmacy graduates, from community and hospital practice to positions with drug companies to work in the Public Health Service. In addition to gathering information on a variety of jobs, students were also able to begin making personal contacts with potential employers. Approximately 50 organizations were represented, and the event was attended by over 150 students, 80 of whom came back from rotations for the event.

The first of two important annual lectures at the School of Pharmacy took place on March 1. This year's Howard Q. Ferguson lecturer was Joseph DiPiro, PharmD, and his talk was entitled "Biotechnology: Cytokines in Clinical Medicine." Dr. DiPiro is Panoz Professor of Pharmacy at the University of Georgia College of Pharmacy and Clinical Professor of Surgery at the Medical College of Georgia. His interests are in pharmacotherapy instruction, studies of the immune disregulation that occurs as a consequence of trauma and sepsis, and in clinical trials of new agents to treat or prevent infection in surgical and trauma patients. Among his many publications, Dr. DiPiro is probably most well-known as founding editor of the textbook *Pharmacotherapy: A Pathophysiologic Approach*, required reading for ALL pharmacy students! The lecture was attended by students and faculty in health affairs programs and was followed by a reception where attendees got a chance to talk with Dr. DiPiro in person.

The Lilly Lecture Series is scheduled to begin Friday, April 9, in Beard Hall on campus. The featured speakers will be Kristine Harper, MD, and Pat McCollam, PharmD, who will be speaking on "Issues in Women's Health." Dr. Harper is a Clinical Research Physician at Eli Lilly and Co., and the former Medical Director of the Duke Bone and Metabolic Diseases Clinic. Dr. McCollam is a Health Outcomes Research Consultant at Lilly and a former Assistant Professor and Clinical Specialist in Adult Cardiology at the Medical University of South Carolina.

There will be a reception preceding the talk from 1-3 p.m., in the Student Lounge. The lecture itself will take place 3 p.m. in Beard Hall Room 116. The Lilly Lecture Series is free and open to health care professionals, and we invite you to attend. Please let Gail Moriarity know as soon as possible if you do plan on attending the reception and/or lecture. She be can reached at (919) 962-0099. For further information on upcoming events at the UNC School of Pharmacy, please visit our website at http://www.pharmacy.unc.edu/pharmacy/calendara.html.

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NCSHP members are encouraged to share their views, concerns and ideas with their colleagues by contributing articles to the NCSHP Newsletter. Opinions expressed are those of the author and may not represent the views of NCSHP, its officers, Board of Directors or its membership. Copy deadlines are the 10th of the month prior to the month of the next issue to be published. (i.e. April 10th for the May/June Issue.)

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# *Clinical Consultant's Corner*

## Dental Pharmacy Update

by Lorie L. Poole, BS, PharmD, BCPS, Director of Pharmacy Services, Community General Hospital, Thomasville, NC

More than one-third of patients seeking dental treatment today have some form of gum disease or periodontitis. As patient education has increased, dental caries have decreased. Still, tooth decay is a major concern.

In addition to traditional periodontal treatments, a few new dental products are being used. Today, a promising vaccine for dental caries is in trial. The vaccine is a plant-based substance that is painted on teeth and produces antibodies that prevent harmful bacteria such as streptococcus mutans from sticking to the teeth and causing cavities. During clinical trials, the participants received the vaccine twice a week for three weeks for a total of six applications. Protection was maintained for up to four months. It is still early for complete information on the vaccine, however, the company is anticipating having the vaccine available in 2001 or 2002.

Periodontitis is a chronic inflammatory disease of the tissues that surround and support the teeth including the gingiva, cementum, periodontal ligament and alveolar, and supporting bone. Without proper care, periodontitis can lead to tooth loss. Treatment of periodontitis involves primarily scaling and root planing which is smoothing or cleaning the subgingival root surface free of calculus and debris.

In conjunction with the traditional regimen, several new products are available to dentists to aid in treatment of periodontitis. Periostat is an oral capsule manufactured by CollaGenex. The active ingredient in each capsule is doxycycline hyclate 20mg. The low dose doxycycline is used to inhibit collagenase, an enzyme that destroys connective tissue in the gums. Dosing requires twice daily administration. Duration of therapy is individualized by the clinician's judgment. Efficacy of therapy has been seen after three months of continuous dosing. Efficacy beyond nine months and safety beyond 12 months of continuous dosing have yet to be established.

Atridox (doxycycline hyclate, 10 percent) is a subgingival controlled-release product composed of a two-syringe mixing system. The antibacterial effect is a key part of Atridox's efficacy. The constituted product is a viscous liquid that solidifies once applied to the periodontal pockets around the teeth and it allows for controlled release of drug over seven days. No anesthesia is required for administration and removal is not necessary since the antimicrobial gel is bioabsorbable. Patients should be instructed not to perform mechanical oral hygiene procedures such as brushing or flossing on any treated areas for seven days.

Actisite is another similar product and has been available for three years. The tetracycline 25 percent fiber-filled product is placed subgingivally. The medication is continuously released over 10 days. The tetracycline-immobilized, crossed-linked collagen film (TC film) remains clinically and bacteriologically effective for two to three weeks. Patients should be instructed not to floss around treated areas for 10 days. Additional counseling tips for tetracycline and doxycycline products include: avoid excessive sunlight, effectiveness of birth control pills may be decreased and avoid antacids or supplements that contain calcium, magnesium, aluminum or iron.

The Perio-chip is a delivery system composed of a biodegradable chip of hydrolyzed gelatin impregnated with 2.5 mg of chlorhexidine gluconate. Because chlorhexidine is poorly absorbed through the mucosa, the efficacy of the antimicrobial activity is primarily a topical effect. The chip is effective for at least seven days once implanted into deep periodontal pockets (>5mm). Treatment intervals are recommended every three months. No anesthetic is necessary for placement. The product requires refrigeration. Flossing is not recommended for 10 days around the implanted chip. There have not been any serious adverse events. The most commonly reported adverse effect was toothache, up to 51 percent compared to 41 percent in the placebo group. Whereas the chlorhexidine oral rinse's most common adverse effect is tooth staining, the perio-chip does not have any visible tooth staining.

Combination treatment medications as discussed with scaling and root planing are used to reduce bacterial counts, gain periodontal ligament attachment and reduce periodontal pocket depth. A good periodontal maintenance program, along with good oral hygiene and scaling and root planing, are necessary to help maintain viability of the teeth. With mechanical debridement as the initial treatment standard of care, it is up to the clinician to decide when one of these products should be applied. Since each of these products has a different mechanism of action, time will show which, if any, are effective and used in the treatment of this chronic disease.

## Pharmacist-Managed Anticoagulation Clinic Success in Concord, NC

by Rebecca J. Millan, PharmD, and
Elise M. McInnis, PharmD,
NorthEast Medical Center,
Concord, NC

Oral anticoagulation therapy is complicated and requires detailed management to ensure adequate therapeutic outcomes. Traditionally, the patient's primary care physician has managed anticoagulation therapy. The patients would have their blood drawn by the laboratory then go home and wait for the results. The laboratory would contact the physician's office with the protime (PT)/INR, and the physician would make the necessary adjustments. Finally, the patients would either retrieve the dosage changes from a recorded message via telephone or from the nurse via telephone. For the patients, this is an all day process with little face to face contact with a health professional. For the physicians and nurses, this is a time consuming daily duty for which they receive no reimbursement.

Over the last 10 years, numerous studies have demonstrated coordinated anticoagulation therapy as being similar or superior to traditional management with regard to therapeutic outcomes. Pharmacist-managed anticoagulation clinics are becoming recognized as an asset to the physicians by removing an unpaid burden while improving the quality of care provided to the patients. In "Coumadin® clinics," patients are seen in person, therefore, under certain circumstances, an office visit may be billed to the insurance carrier.

Copperfield Internal Medicine, employing six physicians, is owned and operated by NorthEast Medical Center. Anticoagulation therapy was managed by the traditional method. The physicians expressed an interest in changing the management of their patients' anticoagulation therapy. The department of pharmacy and the physicians met to discuss how to improve warfarin therapy in their clinic.

The pharmacy received a grant from the NorthEast Medical Center Foundation to pilot a pharmacist-managed anticoagulation clinic in the physicians' office. The monies initially funded operational costs: pharmacist certification and salary, two Coaguchek® point-of-care devices, computers to run the Coumacare® patient management software and testing supplies (lancets, strips, alcohol pads, etc). Coumadin® protocols were developed by the pharmacists and approved by the physicians. All of the physicians' patients (n=210) were referred to the clinic and notified by letter from the clinic. Appointments were established in 15-minute intervals. At each visit, the patient's INR is obtained by fingerstick and evaluated per protocol. The patients are questioned about bleeding, signs of thromboembolism, compliance and changes in diet, and medications. If necessary, dosage adjustments are made per protocol. A follow-up appointment is scheduled according to the trend of the patient's INR. If an appointment is missed, the patient is contacted to reschedule. Monthly, the patients are charged for an office visit under the physicians provider number per the "incident to" rule of Medicare. If the patients are seen more than once a month, they are charged solely for the laboratory test.

Our primary goal was to establish a pharmacist-managed anticoagulation clinic, which could be financially justified through revenue and cost-avoidance. The current medical literature already suggested that such clinics are financially justified through the "cost-avoided" with improved patient outcomes. A cost-analysis was performed and based on total expenses, revenues earned and associated cost-avoidance. The expenses included laboratory supplies; physician, nurse, laboratory technician and pharmacist salaries, and contractual adjustment for the clinic. The revenue generated by standard care was $40,498 compared to $100,436 generated by the clinic. The total expenses of the clinic exceeded the revenues by $10,151 and $26,227 for traditional care. Associated savings of $36,516 based on physician, nurse and laboratory technician time previously spent on anticoagulation resulted in a labor cost-avoidance of $26,368 per year. Ultimately, the clinic realized a net cost-avoidance of $16,076.

Another goal was to assess the

*Clinic continued on page 26.*

### Calendar of Events

March 21-27, 1999
National Poison Control Week

May 20-22, 1999
NC Pharmacy
Annual Convention
Atlantic Beach

June 6-10, 1999
ASHP Annual Meeting
Reno, Nev.

July 10, 1999
PTCB Exam
Deadline - May 14, 1999

July 31-August 2, 1999
ASHP Home Care Meeting
Chicago, Ill.

September 11-12, 1999
Pharmacy Practice Seminar
Wilmington

October 6-7, 1999
Annual Carolina Seminar
Greensboro

December 5-9, 1999
ASHP Midyear Clinical
Orlando, Fla.

June 4-8, 2000
ASHP Annual Meeting
Philadelphia, Penn.

**PRN**

**Pharmacist Recovery Network**

Do you have a problem? Does a pharmacist or pharmacy student you know have a problem? Could this problem be related to alcohol or drug abuse? If you need help, call

**1-336-774-6555**
**FAX 1-336-774-9010**

You may leave your name / number and your call will be returned promptly.

*Meeting continued from page 21.*

cuss important issues and provide feedback on ideas and progress being made thus far.

After this busy morning, the afternoon session included four more continuing education sessions entitled: "Monitoring Our Patients: Lab Values/ Fluid & Electrolytes", "Diabetes: Beginning the Disease State Management Process", "Women's Health Issues" and "New Medications to Treat CNS Disorders." The evening was rounded out with nine poster presentations and exhibits from 42 different companies — a great time for professional interaction and dinner!

The second day of programming began with two talks on the "Vision for the Future: Unification on the National Scene" presented by Whit Moose, president of the National Community Pharmacists Association (NCPA) and Bruce Canaday, president of the American Society of Health-System Pharmacists (ASHP). David Work, executive director of the North Carolina Board of Pharmacy, presented the newest updates on pharmacy law in our state. The title of the talk held itself to be true as these rules are ones that *enable* pharmacists for a change, addressing issues such as pharmacist work conditions, emergency prescription refills and automated dispensing.

The pharmacist network update completed the morning program. The afternoon program contained two workshop sessions. Pharmacists were able to attend workshops on a variety of topics including investment and retirement planning, immunizations, herbal medicines, and asthmatic and diabetic patient assessment.

With 265 pharmacists, 76 technicians and 5 students, the attendance at this meeting was somewhat smaller than in previous years, however, the content was outstanding. Pharmacists in this state needed to be informed of the changes to the state pharmacy organization structure and the progress that was being made towards this end. In addition, they were given the opportunity to attend sessions that would be helpful regardless of what setting they practice in. The face of pharmacy in North Carolina is truly changing — for the better!

*Clinic continued from page 25.*

quality of care of the pharmacist-managed clinic. In order to do this, six months of clinic data was compared to the preceding six months of traditional care. Data included percentage of patients' therapeutic, average number of visits/month, assessment of compliance and patient satisfaction. The results of the data are listed in Table 1. It is difficult to assess a change in the hemorrhage or thromboembolic event rates, as we did not have a control group. This has not been formally assessed.

Table 1

| | Standard Care | Pharmacist-Managed Clinic |
|---|---|---|
| Patients | n=210 | n=262 |
| Therapeutic INR ±0.2 | 69.67% | 71.13% |
| Average visits/month | 356.8 | 389.2 |
| Average visits/pt/month• | 1.7 | 1.5 |
| Patients non-compliant•• | 73 | 1 |

• *Decrease of 2.4 visits/pt/year*

•• *Missed at least 50 percent of appointments by more than 7 days*

The percentage of patients being maintained as therapeutic increased by 1.5 percent, despite the 16.6 percent increase in the number of clinic patients. As a result of the increased patients, the average number of visits per month increased. It is important to note that if the data is extrapolated for the year, the number of visits per patient decreased by 2.4. Another area that has shown improvement is patient compliance. As noted in Table 1, 73 patients in the standard care group were non-compliant compared to 1 in the clinic group. This improvement is accounted for by personal telephone calls made when appointments are missed. Patient satisfaction was an important issue addressed through a survey.

The survey was helpful in establishing the acceptance of the anticoagulation clinic by the patients. As seen in Table 2, 60 percent of patients were confused about their Coumadin® dose in the standard care group. The confusion was often due to the recorded telephone message that the patients called to get dosage changes. Some patients stated they could not understand the message. With the clinic, the changes are made in person, and the patient can ask questions if he/she is uncertain of the dose. Also, a dosage schedule is given to the patient with each dosage change. The patients stated through the survey that they prefer the pharmacist-managed clinic to the standard of care. Most patients like the one-on-one contact and the personal attention they receive from the pharmacist. It was also reassuring that 97 percent of patients are comfortable with pharmacists managing their Coumadin® therapy.

Table 2

| Survey results• | Standard Care | Pharmacist-managed care |
|---|---|---|
| Confused about the dose | 60% | 1.6% |
| Preferred method of care | 1.6% | 98.4% |
| Comfort with Pharmacists | NA | 97% |

• *(35% responded)*

The patients, physicians and administrators of NEMC view the pharmacist-managed anticoagulation clinic very positively. The clinic has been able to provide a good quality of care and patient satisfaction while being financially justified by administration. As a result of the clinic's success, another pharmacist-managed anticoagulation clinic is being established at NEMC. The anticoagulation clinic has been an effective vehicle for the pharmacy's expansion of clinical services by allowing in-patient pharmacists to participate in ambulatory care services.

The results reported in this paper will be presented in a platform presentation at the International Congress on Clinical Pharmacy sponsored by the American College of Clinical Pharmacy and the European Society of Clinical Pharmacy in Orlando, Fla., on April 11, 1999.

# INDUSTRY

## A Pharmaceutical Company's Perspective

Jeff Peterson, RPh, MBA
Director, Strategic Operations, Professional & State Government Affairs, Glaxo Wellcome Inc.

It looks like 1999 will be a very busy year legislatively for pharmacists and pharmaceutical companies. In North Carolina, the landscape has changed a little in that the Democrats have taken control of the House from the Republicans. This could mean more opportunities for legislation affecting health care, or it could have no effect at all.

Both nationally and in the states, there are several issues that the industry will be watching, and some that we may try to take a proactive role in. On the national scene, the debate over a Medicare Drug Benefit is something that pharmacists and the pharmaceutical industry will have a keen interest in. The expected increase in the utilization of pharmaceuticals will have to be balanced against the reimbursement rates, rebate liabilities and deductibles, co-pays, and eligibility requirements. The same issue of a drug benefit for low-income elderly is being considered by the states. Currently, eleven states have some type of expanded drug coverage program for the elderly, and according to the National Council of State Legislatures (NCSL), twenty-seven states have indicated that this will be an issue addressed this year. North Carolina is one of the states where it is anticipated that an Elderly Drug Assistance Program will be debated this year.

Scope of Practice issues promise to be an important topic this year. Nationally, and in many of the states, pharmacists and nurses are seeking to expand their roles beyond what they traditionally have been considered. This presents a tremendous opportunity for pharmacists, nurses, physicians and the pharmaceutical industry to work together to craft legislation that most greatly benefits the people that are responsible for all of us being here . . . the patients.

Probably the most important legislative activity regarding health care this year will revolve around patient confidentiality and medical records. This promises to be a topic on the national scene, as well as in many of the states, including North Carolina. From an industry perspective, we support the protection of patient confidentiality, while at the same time protect the ability of companies to conduct research. The commercial use of medical records is something that pharmacists and the pharmaceutical industry will need to pay close attention to. Examples of commercial use topics in the confidentiality discussion will include use of records for compliance programs, disease-management programs and market research or marketing initiatives.

Other types of legislation that the industry will be watching this year will include cloning, genetic information bills, Medicaid prior authorization, supplemental rebate proposals for state programs, Ryan White Care Act funding, tort reform and tax reform. It will also be very important to watch what happens at the federal and state levels regarding the tobacco settlement. Monies from the tobacco settlement could provide an excellent opportunity for states to develop preventative health programs in which pharmacists could collaborate with the state, other health care professionals and the pharmaceutical industry in program development and implementation. At Glaxo Wellcome, we are certainly interested in looking at these types of opportunities in the areas of asthma, HIV and smoking cessation.

All in all it promises to be an active year. There are some threats, but there are also some tremendous opportunities for pharmacists and the pharmaceutical industry to work together at the state and federal levels. We look forward to continuing our great relationships with the pharmacists, and to building the best health care system in the world by working together.

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*ASHP continued from page 21.*

reform will be considered by the 106th Congress. Medical and allied health profession residencies are currently eligible for reimbursement under the Medicare program. Both the Bipartisan Commission on the Future of Medicine and the Medicare Payment Advisory Commissions — two Congressionally chartered commissions — will report later this year on policy options for GME. ASHP and other pharmacy organizations have commissioned a report, "A Case for Public Support of Pharmacy Residency Training," recommending that Medicare funding for pharmacy residencies be preserved, that the proportion of funding for pharmacy residencies be expanded and that targeted funding for certain pharmacy residencies be established. ASHP will also be working with its affiliated state societies to obtain similar funding from state governments.

Confidentiality of patients' health care information is also an important issue as Congress nears its self-imposed deadline of August 1999 to pass legislation. ASHP will advocate pharmacist access to patient health records in order to provide quality care and ensure the safe use of medications. With the privilege of that access comes the responsibility to safeguard the patient's right to privacy and confidentiality. ASHP will lobby policy makers to ensure that health-system pharmacists involved in clinical trials or serving as preceptors to pharmacy residencies can access patient health information while maintaining confidentiality.

ASHP and other pharmacy organizations will advocate pharmacist reimbursement for professional services as part of a Medicare prescription drug benefit. ASHP will also continue to advocate recognition of pharmacists as providers under Medicare in order to obtain reimbursement for services such as diabetes self-management, other disease state services and other collaborative drug therapy management services.

These are just a few of the government affairs issues that ASHP will be advocating for its members on Capitol Hill, in federal agencies and through its affiliates at the state level. For more information, visit ASHP's web page (*www.ashp.org*).

# Dilemmas

## What is the Value of Pharmaceutical Care?

by Tracy DeWald, PharmD, Pharmacy Practice Resident, Duke University Medical Center

Pharmaceutical care is not a new concept in the pharmacy profession. It was first described by Hepler and Strand in 1990[1], when they introduced the concept of expanded services and responsibilities by pharmacists. Implementation of this concept has been challenging for every area of pharmacy practice. The past decade has witnessed the greatest degree of growth in drugs approved and marketed, demanding an equally extensive knowledge of drugs and pharmacotherapy. Along with this degree of growth in the profession, pharmacists have assumed the responsibility for providing patient-focused care, rather than product-focused service. The same time period has witnessed a new educational standard as the Doctor of Pharmacy degree has become the new entry-level degree. Few other professionals would be expected to provide extensive services without financial compensation. Shouldn't pharmacists also be reimbursed for the provision of expanded services and greater educational requirements?

The decision by pharmacists to pursue reimbursement for value-added services has become a dilemma to many. Primary considerations include the question of who will provide reimbursement and how to determine what fee should be attached to a particular service. Unlike drug inventory, cognitive services are intangible and difficult to quantify monetarily, despite the potential revenue that can be generated and costs that may be minimized by these services. Schumock et al. reviewed economic assessments of clinical pharmacy services from 1988-1995. They reported one controlled evaluation which documented a net savings of $377 per patient admission as a result of clinical pharmacists interventions on an inpatient medical service. Additionally, of the articles which reported benefit-cost ratios, the calculated results ranged from 1.08:1 to 75.84:1 (mean 16.7:1).[2] Other factors which make value-added services difficult to manage, and ultimately market, are the variability in the services at the provider level and the inability to separate the production of the service with delivery and consumption as is typically done with products.[3]

Traditionally, attempts to seek reimbursement for cognitive services have been thwarted by a refusal to provide reimbursement on the behalf of third party payers since these services are already provided at no charge. Also, limited outcomes data have been generated to support the benefits of value-added services with respect to patient outcome, quality of life, satisfaction, self-care and compliance.

Which activities are considered value-added services? According to Shepard, value-added services make an existing product, service or information more useful to the patient or consumer of those services.[3] In pharmacy, the consumer could be patients, physicians, other health care providers, managed care organizations or third party payers. Examples of value-added services include selection of the most cost-effective products, assisting physicians with the management of patient medication regimens, disease management, formulary management, drug interaction assessment and monitoring with follow-up care to patients. This includes assessing patient compliance, adverse effects, optimal dosing and therapeutic efficacy. Other value-added services may include specialized group classes such as smoking cessation classes, asthma management or "brown bag" sessions for patients taking multiple drug regimens. Regardless of the specific services that are provided, successful provision of value-added services must include several elements[3]:

- the service must be provided in a timely manner, as perceived by the consumer.
- the service must be accurate and responsive to the consumer's needs.
- the service must meet consumer or patient needs and expectations.
- the service provided must be consistent and reliable.

In other words, the provision of value-added services is driven by consumer demands and needs, and the success of the services is determined by the satisfaction of the consumer.

Pharmacists, like other health care providers, have had to adapt to a changing health care environment over the past decade. In addition to the changing environment, pharmacists have also become responsible for a greater number of drugs, assumed more responsibility for the management of drug therapy and have had to achieve a higher standard of education. This experience and skill has positioned pharmacists to be providers of services which exceed the traditional product-focused services. Many are eager to expand their roles to provide innovative services. Pharmacists should retain the opportunity to obtain financial reimbursement for cognitive services, when the service provided is "value-added." Ultimately who pays or how much is paid is secondary to the possibility that consumers *value* the services provided by pharmacists enough to reimburse them for their expertise. To continue to give our services away without reimbursement will make the possibility of reimbursement in the future less likely. As additional outcomes data are generated in support of decreased hospitalization, reduced length of stay, improved patient satisfaction and improved quality of life as a result of pharmacists interventions, we must be ready to pursue the opportunity to obtain reimbursement for the magnitude of services we now provide.

*References*

*1. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm 1990;47:533-43.*

*2. Schumock GT, Meek PD, Ploetz PA, Vermeulen LC. Economic evaluations of clinical pharmacy services. Pharmacotherapy 1996;16(6):1188-1208.*

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# Where the Rules on Pharmacists' Working Conditions Stand

David Work
Executive Director

At the June 1998 meeting of the Board of Pharmacy in connection with the licensure exam, the members first raised the issue of considering a rule requiring employers to give pharmacists meal breaks and rest periods and prohibiting employers from requiring pharmacists to work longer than 12 continuous hours in any work day. Board staff was directed to publish text of the rule which occurred on Aug. 14, 1998. The text of the rule reads:

> .2506 Pharmacist Work Conditions
> "A permit holder shall not require a pharmacist to work longer than 12 continuous hours per work day. A pharmacist working longer than 6 continuous hours per day shall be allowed during that time period to take a 30-minute meal break and one additional 15-minute break."

A public hearing was scheduled on Sept. 14, 1998, at the Institute of Pharmacy, and many people commented on the proposal. Representatives of one chain store commented that there is no correlation between workload and prescription errors and that work or meal breaks will just cause pharmacists to get farther behind in filling prescriptions. They noted that the same amount of prescriptions would need to be filled in less time, and a break in pharmacy services could jeopardize patient needs. They also raised the question of whether patients could pick up prescriptions that had already been filled by the pharmacist during the break period.

The National Association of Chain Drug Stores commented that voluntary quality improvement programs would be better at accomplishing the goal of optimizing patient care and decreasing errors. Representatives from a health maintenance organization commented that this is a personnel issue that should be resolved between employers and employees. A hospital pharmacy representative noted that the effect of the proposed rule would allow wages to be deducted for pharmacists paid on an hourly basis, but not those on a salary basis, and this would be unfair. Numerous pharmacists commented in support of the rule, and the North Carolina Association of Pharmacists supported the proposed rule.

The Pharmacy Board adopted the proposed rule on Oct. 27, 1998, and the text was sent to the Rules Review Committee for their consideration.

At the Dec. 17, 1998, meeting of the Rules Review Commission, its staff recommended that they object to the rule, effectively stopping its progress. The only input the Commission heard on this issue was from Commission staff. Others, including counsel and the Executive Director of the Pharmacy Board, were not given the opportunity to comment. The Commission voted unanimously to object to the rule and return it to the Board for further action.

At the Jan. 19, 1999, meeting of the Board of Pharmacy, it was their unanimous vote to complete the administrative procedures on this matter which involved returning the rule for further consideration on Feb. 18, 1999. The members further directed staff, absent of any changes from the Commission, to proceed with judicial review of the matter in the court system.

On Feb. 18, 1999, the commission reconsidered, but did not change its decision of December 1998. Many comments were received by the Board from individual pharmacists, including:

- "I started in retail because it afforded me the opportunity to be always at the patient's level. I was readily accessible to them and was full of useful knowledge to share to enhance their lives. But working 12-hours a day, filling 250-300 scripts and not being able to leave but once to answer nature's call has taken its toll on my attitude and perspective. The system just doesn't allow for effective counseling, and doesn't allow for pharmacists to be humans in need of time to eat and just to be away from the pressures of the bench if only for an hour."
- "I recently observed a pharmacist work for approximately three months, open and close, seven days a week with no relief because there were no replacement pharmacists. The management did nothing to send in relief. Finally, the pharmacist found a relief person that spelled him occasionally but it was nearly six months that he endured that pressure. Situations like this should absolutely not be allowed to happen."
- "My wife and I and all the pharmacists we know are solidly behind the Board as regards to its position on the lunch breaks for pharmacists. As one pharmacist put it, 'Even the man who sweeps the floor gets a lunch break' not to mention farm animals or convicts."
- "Even migrant workers have better working conditions than pharmacists."

The members are committed to pursuing this issue as a matter of public safety. Pharmacists working long hours without rest or meal breaks are plainly a danger to the public health and safety. As this matter has progressed some employers have voluntarily adopted meal breaks which certainly is a step in the right direction.

## ~ NOTICE ~

### Rule Repair

The Board has adopted a rule on automated dispensing devices including, but not limited to, Pyxis machines. Somewhere in the rule-making process a phrase was dropped, and the adopted rule appears to require a computerized interface with the pharmacy and automated dispensing devices such as a Pyxis machine in order to perform limited drug use review.

The adopted rule appears to provide for something which was not intended by the Board and will be repaired at the first opportunity. Notice will be given of a proposed change in the rule in April of this year to be effective at its earliest possible date which should be some time in the year 2000.

Further developments can be observed at the Board's web site www.ncbop.org.

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# Patient Counseling: New Drugs of 1998: Plavix, Avapro and Teveten

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Goals. The goals of this lesson are to identify and discuss new drugs approved by FDA in late 1997 and introduced to the marketplace during 1998.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge of the pharmacologic classification and therapeutic considerations for the drugs presented;
2. select from a list, the indication, mechanism of action, benefits and limitations of these drugs;
3. identify adverse reactions, major toxicities, and drug interactions associated with these products; and,
4. demonstrate an ability to counsel patients on these drugs.

A professional development program made possible by an educational grant from

SEARLE

Gossel

Wuest

**Clopidogrel (Plavix)**

Clopidogrel [Clo-pid-o-GREL/Plaa-VICKS] is a platelet aggregation inhibitor that directly inhibits adenosine diphosphate (ADP) from binding to its receptor sites on platelets. It is available in 75mg tablets.

**The Disease.** To review the clotting mechanism, when blood vessels are injured, the body's initial defense to prevent excessive blood loss stimulates platelet aggregation in the vicinity of the event, and releases chemicals involved in the clotting mechanism. This process allows platelets to clump together over the injury to form the "hemostatic plug." This covers the opening, prevents excessive blood loss, and initiates the formation of the permanent fibrin clot.

While this is necessary for hemostasis, the same events can occur excessively (and without a precipitating injury) in the arteries of patients with atherosclerosis and other clotting disorders leading to unwanted blood clot (thrombus) formation. When a thrombus breaks loose from its anchor at the point of formation on the blood vessel wall, it travels with the blood flow as an embolus into narrower passages (i.e., arteries to arterioles to capillaries) to the point where it is too large to move. There it lodges, and blocks the advance of blood and oxygen to tissues supplied by that blood vessel.

Since cells supplied with oxygen from the blood cannot live in its absence, they will soon die. In many areas of the body, there is sufficient collateral circulation to provide adequate blood flow into that area and there is little, if any, permanent tissue damage.

However, when a sufficient number of thrombi form and break loose (thromboembolism) to lodge in and prevent proper blood and oxygen supply to an end organ, the system is overwhelmed. The cells deprived of oxygen die (tissue necrosis) and the function they perform is lost.

The two organs that are affected most significantly are the heart and brain. Inadequate blood and oxygen supply (ischemia) to the heart can lead to sufficient tissue necrosis (myocardial infarction) to initiate arrhythmias. Because the heart's tissue is not able to conduct electrical impulses or contract properly, ventricular tachycardia and death can result.

In the brain, ischemia and tissue necrosis lead to a loss of function of the affected area. The result is a stroke (cerebrovascular accident), which if extensive can also cause death.

Another morbid result of thromboembolism is excessive blockage of blood vessels in the lungs (pulmonary embolism). This can lead to severe cardiac congestion and death. Peripheral vascular diseases are also aggravated by excessive platelet aggregation.

**Therapy.** Patients with a tendency toward thromboembolism, especially those who have suffered from and survived a myocardial infarction, are treated prophylactically with platelet aggregation inhibitors (PAI). Currently, there are several different types of PAI. The three most commonly used are aspirin, dipyridamole and ticlopidine (Ticlid). Clopidogrel's action is similar to ticlopidine but totally different from aspirin and dipyridamole. Commercially available platelet aggregation inhibitors are listed in Table 1.

Aspirin inhibits platelet cyclooxygenase which prevents the formation of thromboxane $A_2$, one of the mediators of platelet aggregation. Reducing the formation of thromboxane $A_2$ reduces platelet aggregation, and lessens the chance of excessive clot formation.

Dipyridamole is a phosphodiesterase inhibitor with reported selectivity to the type of phosphodiesterase contained in platelets. Inhibiting this enzyme reduces the breakdown of cyclic adenosine monophosphate (cAMP) in the platelets, which also lessens platelet aggregation and excessive clot formation.

Plavix (and Ticlid), as stated earlier, inhibit adenosine diphosphate (ADP) from binding to its receptor sites on platelets. Fibrinogen, the precursor to fibrin, is an extremely important component of

### Table 1
### Commercially Available Platelet Aggregation Inhibitors

| Generic Name | Trade Name | Dosage Forms | Usual Dose |
|---|---|---|---|
| Aspirin | various generics | 81, 165, 325mg tablets | 325mg once daily |
| Clopidogrel | Plavix | 75mg tablets | 75mg once daily |
| Dipyridamole | Persantine<br>generics | 25, 50, 75mg tablets | 75-100mg q.i.d. |
| Ticlopidine | Ticlid | 250mg tablets | 250mg b.i.d. with food |

permanent clot formation. Fibrinogen is soluble in the blood and is always ready to be converted into fibrin when needed.

This conversion is initiated by the chemicals released from platelets when they aggregate and lyse. Fibrin is insoluble. When formed, fibrin precipitates and adheres to the hemostatic plug to eventually surround it. This becomes the permanent clot. Fibrinogen itself induces platelet aggregation by binding to a glycoprotein complex on the surface of the platelets.

The binding of fibrinogen to this complex is activated by ADP. Clopidogrel forms a selective, irreversible bond with this same complex for the life of the affected platelet. This, then, inhibits the ability of fibrinogen to induce platelet aggregation.

Plavix was given priority consideration for approval by the FDA because it is considered to have a better safety profile than ticlopidine since it does not induce adverse hematologic reactions. It also causes less gastrointestinal upset and hemorrhage than either ticlopidine or aspirin. It was approved on the basis of a single clinical trial, only eight months after its New Drug Application was submitted to FDA, which is unusual.

Plavix is expected to be a highly prescribed platelet aggregation inhibitor. Its safety when used concurrently with aspirin has not been tested. Since it has a different mechanism of action than aspirin, it is anticipated that physicians will use both drugs concurrently for many patients.

**Adverse Reactions.** Adverse reactions reported for clopidogrel at 5 percent or more include: indigestion, nausea, vomiting and bleeding. It is contraindicated in patients with any active pathological bleeding disorder such as peptic ulcer disease or intracranial hemorrhage.

**Drug Interactions.** At the time of its approval, Plavix had not demonstrated any clinically significant drug interactions. It had not been studied in co-administration with warfarin, but it had no noticeable effects on heparin. Aspirin did not increase the platelet inhibition effects of clopidogrel significantly, but clopidogrel did potentiate aspirin somewhat. Clopidogrel increased occult blood (oxidized blood in feces) loss caused by naproxen.

In very high concentrations, clopidogrel inhibits cytochrome P450 (2C9) so there is a possibility it may inhibit the metabolism of some NSAIDs, fluvastatin, phenytoin, tamoxifen, tolbutamide, torsemide and others. The bottom line is that there are no contraindications to concurrent use of these drugs with Plavix, but they should be used cautiously along with patient monitoring.

**Indications and Dosing.** Plavix is indicated for the reduction of atherosclerotic events (myocardial infarction, stroke, and vascular death) in patients with atherosclerosis documented by recent stroke, recent myocardial infarction, or established peripheral arterial disease.

The usual adult dosage for Plavix is 75mg once a day with food or on an empty stomach.

**Patient Advice.** Patients taking Plavix should be advised to take the tablets every day as directed by their physician.

They should not self-medicate with aspirin-containing OTCs without first consulting with their physician. They should be advised to read the labels of OTCs carefully to avoid aspirin- and salicylate-containing products such as Bufferin, Doan's Pills, Excedrin, Pepto-Bismol, etc. They should not take any herbal dietary supplement before determining if it can enhance the effects of anticoagulant drugs.

Patients should be advised that it may take longer than usual to stop bleeding when they take Plavix, and that they should report any unusual bleeding to their physician. They should inform physicians and dentists that they are taking Plavix before any surgery is scheduled and before any new drug is taken.

### Eprosartan (Teveten) and Irbesartan (Avapro)

Eprosartan (Tevetan) [Epp-roh-SAHR-ton / TEA-vee-ten] and irbesartan (Avapro) [Erb-ah-SAHR-ton / Ava-PRO] are the third and fourth angiotensin II receptor blockers to be approved in the U.S. They join Cozaar and Diovan in this category.

The initial indication for these drugs is the treatment of hypertension. As with Cozaar and Diovan, however, there is evidence that they are also beneficial in the treatment of congestive heart failure and possibly diabetic nephropathy as well. Avapro is available in 75,150 and 300mg tablets and Teveten comes in 300 and 400mg tablets.

**The Disease.** Hypertension is the most prevalent cardiovascular disease in the U.S., reportedly affecting 25 percent of adults. Hypertension is a risk factor for atherosclerosis, coronary heart disease and stroke. Long term, uncontrolled hypertension, even if mild, increases the mortality rate.

In spite of the fact that there are nearly a dozen different pharmacologic groups of drugs (many of which are synergistic to each other) available to control hypertension, fewer than one-fourth of currently treated patients receive adequate control of their condition with these agents.

This points to the need for better monitoring of patients and better compliance on their part. The angiotensin II receptor blockers are aimed at improving compliance because of their relatively low order of adverse reactions.

**Therapy.** As stated above, there are a number of different pharmacologic groups of drugs available for treating hypertension (Table 2). Those of first choice in treating mild, essential hypertension are the thiazide diuretics, beta-adrenergic blockers, calcium channel blockers and angiotensin converting enzyme inhibitors.

The next level of therapy, should a

### Table 2
### Representative Drugs Used to Treat Hypertension

**Thiazides and Thiazide-like Diuretics**
Hydrochlorothiazide
Indapamide

**Beta-Adrenergic Blockers**
Acebutolol (Sectral)
Atenolol (Tenormin)
Betaxolol (Kerlone)
Bisoprolol (Zebeta)
Carteolol (Cartrol)
Labetalol (Normodyne, Trandate)
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(Adalat CC)
Verapamil (Calan SR, Verelan, Covera HS)

**Angiotensin II Receptor Blockers**
Irbesartan (Avapro)
Eprosartan (Teveten)
Losartan (Cozaar)
Valsartan (Diovan)

**Central Acting Alpha-2 Adrenergic Stimulators**
Clonidine (Catapres)
Guanabenz (Wytensin)
Guanfacine (Tenex)
Methyldopa (Aldomet)

**Peripheral Catecholamine Depleters**
Guanadrel (Hylorel)
Guanethidine (Ismelin)
Rauwolfia (Reserpine)

single drug or a combination of the aforementioned classes not be effective in maintaining proper blood pressure, are the alpha-1 specific peripheral adrenergic blockers, the alpha-2 specific central adrenergic agonists and the various vasodilators such as guanethidine, hydralazine, minoxidil and rauwolfia.

As the names imply, both the angiotensin II receptor (AIIR) blockers and the angiotensin converting enzyme (ACE) inhibitors involve activity with angiotensin in their mechanisms of action. Unlike ACE inhibitors, the AIIR blockers do not inhibit the formation of angiotensin II which is part of the renin-angiotensin-aldosterone (RAA) system. Angiotensin II is the most potent vasoconstrictor produced in the body. Instead, the AIIR blockers reduce angiotensin II-mediated vasoconstriction in the vascular smooth muscle and the release of aldosterone from the adrenal medulla by blocking its receptor sites in these tissues.

Both of these actions of angiotensin II contribute to elevated blood pressure, so blocking angiotensin II at these two receptor sites lowers elevated blood pressure. What differentiates AIIR blockers from ACE inhibitors to large extent is that the former have a more selective action on the specific receptor sites for elevated blood pressure.

Angiotensin II has many activities in the body over and above the regulation of blood pressure. It acts on many organs and body systems including the heart, brain, lungs and liver. It affects the production/blood levels of aldosterone, bradykinin, glucose, HDL cholesterol, prostaglandins, triglycerides and uric acid.

There are at least two subtypes of angiotensin II receptors: angiotensin I (AT1) and angiotensin II (AT2). The ACE inhibitors are nonspecific for these receptors because they inhibit the initial formation of angiotensin II. The AIIR blockers are somewhat specific to the AT receptors, which are found in vascular smooth muscle and the aldosterone-producing areas in the adrenal gland. They do not significantly affect the angiotensin receptors in other tissues.

Because of this, it is difficult to differentiate the antihypertensive effects of the ACE inhibitors and AIIR blockers. The difference is in the adverse reactions they cause. With the ACE inhibitors, the most morbid (but very rare) adverse reaction is angioedema. This is a condition of severe subdermic edema (thought to be caused by excessive levels of bradykinin) which can cause intense pain, discoloration and disfigurement of skin, especially in the face.

A more prevalent, less morbid, but extremely annoying adverse reaction to the ACE inhibitors is a dry, persistent cough which many patients will not tolerate. This, too, involves bradykinin.

To review, there is a balance between vasoconstriction and vasodilation in the RAA system which maintains hemostasis in healthy individuals. The vasoconstriction side of the scale involves angiotensin II. The vasodilation side involves bradykinin, a potent vasodilator which is also a part of prostaglandin production.

Angiotensin converting enzyme catalyzes the formation of angiotensin II as well as the breakdown of bradykinin. Therefore, the inhibition of ACE can lead to excessive accumulation of bradykinin by reducing its breakdown. This in turn leads to excessive formation of prostaglandins. Since most of this activity occurs in the lungs, the increased level of prostaglandins irritates respiratory tissue and the body responds by coughing.

Because the AIIR blockers reduce the activity of angiotensin II at its receptors in the vascular smooth muscle and adrenal medulla, they do not affect bradykinin levels. Therefore, they do not cause the annoying cough and are more acceptable than the ACE inhibitors.

Regarding their place in the market, the original AIIR blocker (Cozaar) did not have as immediate an impact as some authorities anticipated. However, since its release, sales have steadily increased. Its current position is in the top 100 drugs dispensed, and its combination product containing hydrochlorothiazide has reached the top 200 list this past year.

Adverse Reactions. The AIIR blockers are well tolerated with no adverse reactions reported at 5 percent or more, and none significantly higher than that seen in patients receiving the placebo. For example, in 5,000 patients in the irbesartan trials, only 3.4 percent withdrew due to unacceptable adverse reactions. In the placebo-treated group, 4.5 percent dropped out due to unpleasant adverse reactions. A similar outcome was seen with Cozaar.

This class of drugs (including Cozaar and Diovan) has the same boxed warning about pregnancy as the ACE inhibitors, even though they were not tested in pregnant women. All drugs affecting the RAA system directly must carry the following boxed warning in their professional labeling (package insert):

"WARNING: USE IN PREGNANCY: When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death in the developing fetus. When pregnancy is detected (drug name) should be discontinued as soon as possible. See WARNINGS: Fetal/Neonatal Morbidity and Mortality."

Drug Interactions. No significant drug interactions were reported in clinical trials for these two drugs.

Indications and Dosage. Both Avapro and Teveten are indicated for treating mild to moderate hypertension. The usual adult dose for Avapro is 150mg once a day with or without food. The usual adult dose of Teveten is 300mg once a day with or without food.

Patient Advice. Patients taking Avapro or Teveten should be advised to take the tablets every day as directed by their physician. Some patients (rarely) experience lightheadedness and faintness. If this occurs, they should be careful driving or operating hazardous equipment or standing too quickly after lying or sitting down.

Patients should not self-medicate with OTC nasal decongestants (ephedrine, pseudoephedrine, phenylpropanolamine) or appetite supressants containing phenylpropanolamine without first checking with their doctor. They should not take any herbal dietary supplement before determining if it can enhance the effects of antihypertensive drugs.

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# Continuing Education Quiz

## Patient Counseling:
## New Drugs of 1998: Plavix, Avapro and Teveten

1. Plavix acts by:
    a. directly inhibiting adenosine diphosphate function.
    b. inhibiting the formation of leukotrienes.
    c. suppressing the formation of prostaglandins.
    d. inhibiting platelet cyclooxygenase.

2. The platelet aggregation inhibitor that should NOT be administered concurrently with Plavix because it has the same mechanism of action is:
    a. aspirin.
    b. dipyridamole.
    c. ticlopidine.
    d. warfarin.

3. The two organs that are most affected by blood clot-initiated tissue necrosis are the:
    a. intestine and spleen.
    b. brain and heart.
    c. kidney and lungs.
    d. liver and spleen.

4. The component of the permanent clot formation mechanism that is insoluble and precipitates to adhere to the hemostatic plug is:
    a. fibrin.
    b. fibrinogen.
    c. plasmin.
    d. plasminogen.

5. The claimed advantage of clopidogrel over ticlopidine is that clopidogrel does not:
    a. inhibit adenosine diphosphate from binding to its receptor sites.
    b. induce adverse hematologic reactions or gastrointestinal upset.
    c. affect the hemostatic plug or the formation of the permanent clot.
    d. inhibit the ability of fibrinogen to induce platelet aggregation.

6. Aspirin prevents platelet aggregation by:
    a. directly inhibiting adenosine diphosphate function.
    b. inhibiting the formation of leukotrienes.
    c. suppressing the formation of prostaglandins.
    d. inhibiting platelet cyclooxygenase.

7. Patients taking Plavix should be advised NOT to self-medicate with which of the following OTCs without consulting their physician?
    a. Diphenhydramine
    b. Pseudoephedrine
    c. Aspirin
    d. Dextromethorphan

8. The previously available product that is most similar therapeutically to Teveten is:
    a. Cozaar.
    b. Mevacor.
    c. Ticlid.
    d. Motrin.

9. The endogenously produced substance that is most involved in the activity of Avapro is:
    a. adenosine diphosphate.
    b. angiotensin.
    c. pepsinogen.
    d. serotonin.

10. The boxed warning for Avapro and Teveten refers to:
    a. heart disease.
    b. liver disorders.
    c. blood dyscrasias.
    d. pregnancy.

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# Small Doses

• The Board of Pharmaceutical Specialties (BPS) announced that the Board of Trustees of the American Pharmaceutical Association (APhA) has appointed **Beverly J. Holcombe**, BCNSP, Clinical Specialist, Nutrition Support, Department of Pharmacy, University of North Carolina Hospitals, to the Psychiatric Pharmacy specialty council. She will serve a 3-year term, with the possibility of reappointment to a second term.

• The Commission for Certification in Geriatric Pharmacy (CCGP) announced that **Tina Bullard** of Lumberton, **Michelle Fritsch** of Burlington, **Peggy McCormick** of Burlington and **Dan Springfield** of Emerald Isle have been accredited as Certified Geriatric Pharmacists (CGP).

• **Dr. York David Garrett, Jr.**, who practiced pharmacy for more than 70 years and was one of Durham's first African-American pharmacists, died of natural causes at his home in December. He was 104. At one time he was the oldest practicing pharmacist in the state.

Garrett held two degrees from Howard University in Washington D.C. He completed his undergraduate degree in 1916 and his pharmacy degree in 1920. He moved from his hometown of Tarboro in the early 1930s to operate the Biltmore Drug Store in Durham with his wife Julia, who preceded him in death by more than two decades. The couple had four children, two of whom are also deceased.

Garrett was known for driving himself to New York to catch a baseball game or a Broadway show when he was well into his 90s. Not long before he died, a friend asked him to write a prescription to live to be 100. Too late Garrett told him, "I'm working on 200."

• **PPD Inc.**, a Wilmington-based pharmaceutical services company, signed a non-binding letter of intent to purchase **ATP Inc.** (formerly Ask The Pharmacist) for about 1 million shares of PPD stock, estimated at more than $30 million. The deal is expected to close by the end of March. ATP plans to move soon from Chapel Hill into a new building in Meridian Park in Durham. ATP will operate as a wholly owned subsidiary of PPD run by **Mary Lynn Bell**, who founded ATP eight years ago.

• The North Carolina Herb Association had its annual winter conference Feb. 19-21, 1999, at the North Carolina Baptist Assembly at Oak Island, NC. **Dr. James A. Duke** of Fulton, MD, noted authority on healing herbs, was the keynote speaker. He spoke on the "Future of Herbs in U.S.," after which he conducted a wild herb walk.

• The Board of Pharmaceutical Specialties (BPS), an agency whose purpose is to recognize pharmacy specialties and certify pharmacists' knowledge and skill, announced the results of the Oct. 3, 1998, specialty certification examinations. **Scott C. Martin** from Fayetteville and **Michael S. Wooten** from Hendersonville were among 207 candidates who were certified in oncology pharmacy. **Donald W. Graff** of Durham, **Jennifer M. Jordan** of Clemmons and **Deanna Moretz** of Charlotte were among 296 candidates who were licensed as Board Certified Pharmacotherapy Specialists (BCPS). **Robert J. Allen** of Raleigh was among 46 candidates certified in psychiatric pharmacy.

• **Dr. Dennis M. Williams**, assistant professor of pharmacotherapy at UNC-CH, and **Dr. Dale B. Christensen**, professor and chair of pharmaceutical policy and evaluative sciences at UNC-CH, have been named 1999 Fellows of the American Pharmaceutical Association. Both will be recognized at the Association's 146th annual meeting and exposition in March in San Antonio.

• **Charles Chapman** was recently featured in several North Carolina newspapers for his interesting work in compounding medicines at his own pharmacy in Kannapolis. Chapman said, "I make what the doctor thinks best – things not available commercially. It takes more thought, schooling and work, but you get rewarded for it." Hopefully, the positive exposure will help to educate patients across the state about the unique skills that pharmacists have to offer.

• **Dr. David Work**, executive director of the Board of Pharmacy, stated it best in the Dec. 22, 1998, edition of The News and Observer when he said, "It's a do-it-yourself doc-in-a-box." He was talking about Internet access to prescriptions, some not even available in the United States. One notable example was a Viagra site that promised to ship the little blue impotence pill after an AP reporter answered just one health question and disclosed she was a woman.

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## ANNOUNCEMENT

The NCPhA Resolutions Committee invites resolutions to be submitted in writing by May 1, 1999, for consideration at this year's annual convention in May. All resolutions submitted should contain the submitting person's name and daytime phone number. Resolutions should be submitted to: Steve Dedrick, Chairman, 4416 Turnberry Circle, Durham, NC 27712, Fax 919-681-3895 or e-mail **dedri002@mc.duke.edu**.

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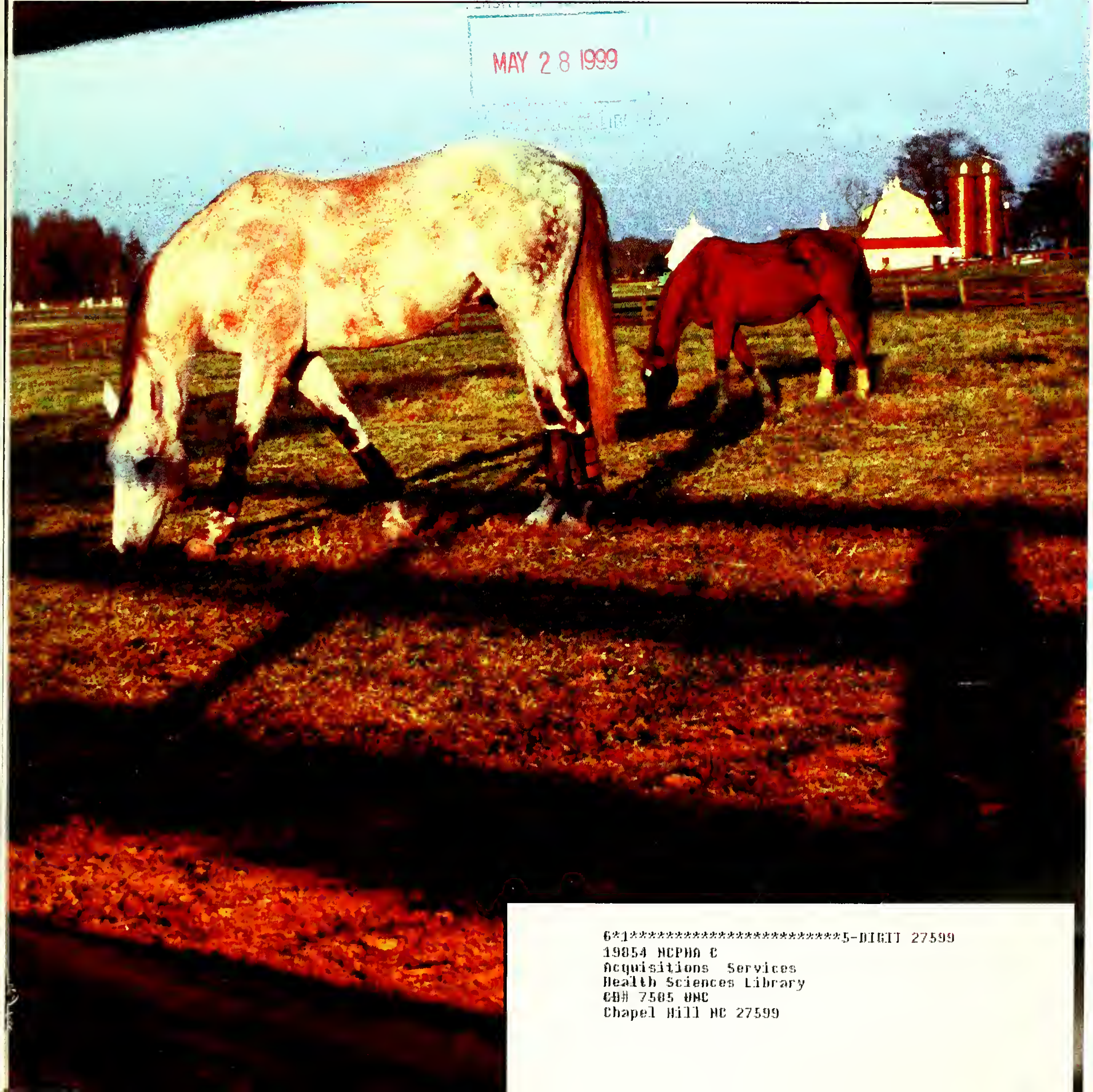

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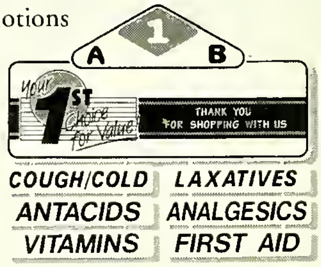

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*Horses at Quail Roost Farm*
*in Rougemont, N.C.*
*Photo by Sara Davis, 1998.*

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# Voice & Vision

Daniel G. Garrett
Executive Director

## "The fear of confrontation leads to the confrontations we fear."

— *Barbara Brown-Taylor, noted priest and professor*

This spring, the Institute for Servant Leadership hosted Archbishop Desmond Tutu at a conference on truth and reconciliation. The other participants and I were challenged to recognize the value of every human being and to realize the first step on the path to freedom is truth. Barbara Brown-Taylor pointed out that fear of confrontation is the greatest obstacle to the truth. When we avoid confrontation we become frustrated, resentful and angry, but healthy confrontation leads to honest dialogue and positive outcomes for those who have the courage to develop creative solutions.

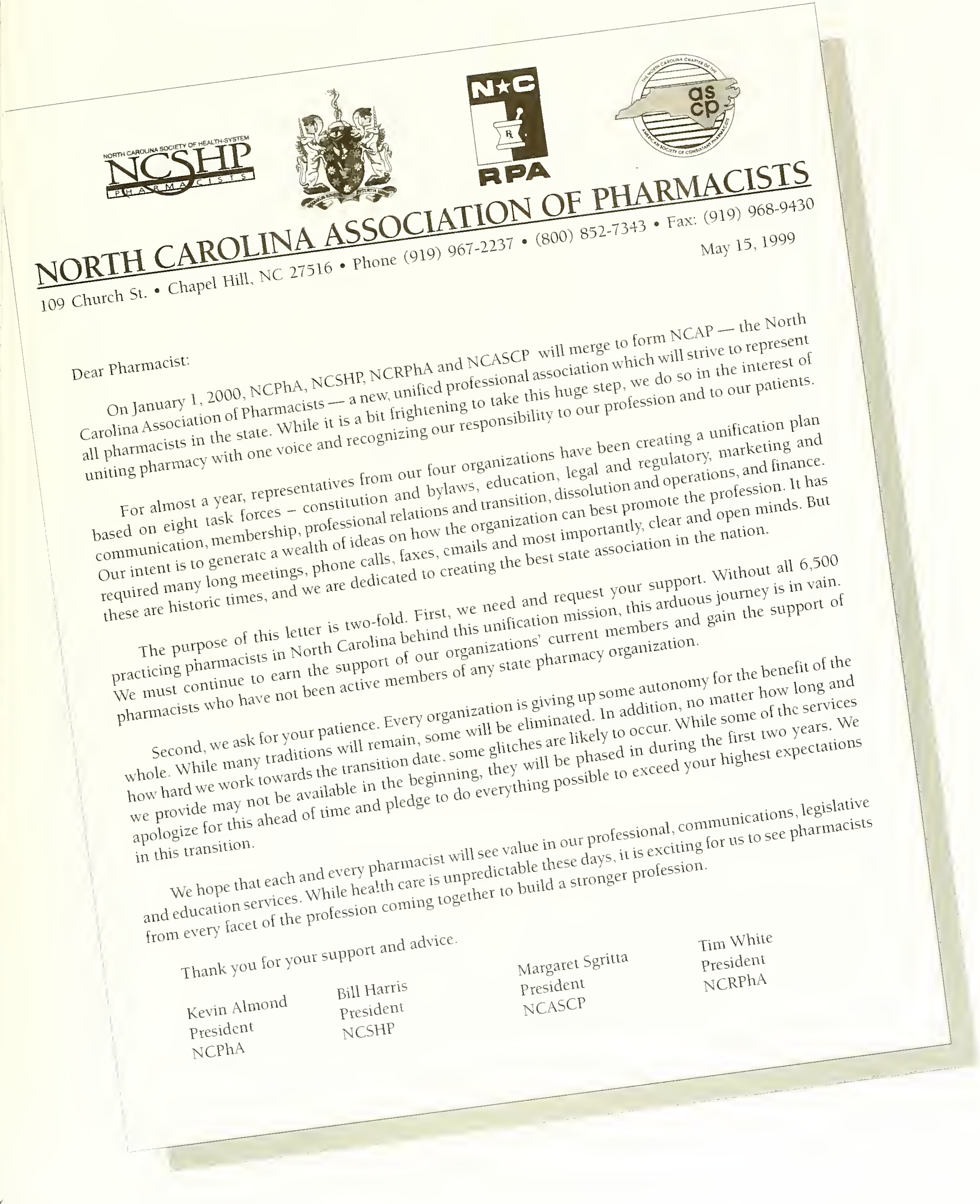
To date, I have attended sixteen local pharmacy association meetings in 1999. At these meetings, I ask pharmacists to think back to the day they graduated from pharmacy school and remember what they hoped to accomplish as a pharmacist. Common responses include: to help people, to share their knowledge about medicines, to own their own pharmacies and be part of the community, to earn a decent living, to be a respected member of the health care team, and to make a difference. When we discuss barriers pharmacists face in fulfilling their personal and professional goals, a few obstacles come up again and again: insurance companies; third-party contracts; volume of work; staff shortages and managed care. Afterward, we discuss technology, patients' desire for personal care and other positive forces in today's environment that are allowing pharmacists to overcome the barriers and meet their professional obligations. Amazingly, by the end of the discussion we realize that many good things are happening in North Carolina Pharmacy which are transforming of our profession.

Many pharmacists across our state are confronting the systems we have been afraid of in the past. In this issue of the *Carolina Journal of Pharmacy,* Chris Rubino describes the first local Independent Provider Association (IPA) for Pharmacists in the country. This landmark effort enables this group of innovators to collectively market and negotiate for clinical pharmacy services directly with payers. The practice profile on Nashville's Gary Glisson describes how a creative practitioner can thrive without the need for third-party plans. Gina Upchurch shares how pharmacists are providing care and medicine for the elderly in Durham. Matthew Milke tells us that pharmacy is now represented as a provider for the North Carolina Children's Health Initiative, and NCSHP President Bill Harris discusses the importance of mentoring in preparing new pharmacists for the challenges ahead. Beth Williams provides an update on the Asheville Project and our plans to replicate this program throughout the state. Sandra Jue describes the use of a new tool to better communicate with patients. These stories are evidence that positive changes are happening.

We have worked hard in the legislature this year and "confronted" insurance companies, managed care and other professional groups which have historically blocked our efforts to advance pharmacy practice and stifle reimbursement for pharmacist services. By the time this *Journal* is published we will know if our work in support of bills to establish clinical pharmacist practitioners, standardize prescription cards, and promote fair competition have paid off.

Why are these positive changes beginning to happen now? I believe it is because pharmacists are realizing that we can "confront" the system. Unification of our professional organizations is helping us gain the confidence we need to push our professional agendas to the forefront. More importantly, our basic desire to help patients is greater than our "fear" of the system.

Please read these stories with pride and join us in healthy confrontation to improve patient care and pharmacy practice in your community. ◎



NORTH CAROLINA ASSOCIATION OF PHARMACISTS
109 Church St. • Chapel Hill, NC 27516 • Phone (919) 967-2237 • (800) 852-7343 • Fax: (919) 968-9430

May 15, 1999

Dear Pharmacist:

On January 1, 2000, NCPhA, NCSHP, NCRPhA and NCASCP will merge to form NCAP — the North Carolina Association of Pharmacists — a new, unified professional association which will strive to represent all pharmacists in the state. While it is a bit frightening to take this huge step, we do so in the interest of uniting pharmacy with one voice and recognizing our responsibility to our profession and to our patients.

For almost a year, representatives from our four organizations have been creating a unification plan based on eight task forces – constitution and bylaws, education, legal and regulatory, marketing and communication, membership, professional relations and transition, dissolution and operations, and finance. Our intent is to generate a wealth of ideas on how the organization can best promote the profession. It has required many long meetings, phone calls, faxes, emails and most importantly, clear and open minds. But these are historic times, and we are dedicated to creating the best state association in the nation.

The purpose of this letter is two-fold. First, we need and request your support. Without all 6,500 practicing pharmacists in North Carolina behind this unification mission, this arduous journey is in vain. We must continue to earn the support of our organizations' current members and gain the support of pharmacists who have not been active members of any state pharmacy organization.

Second, we ask for your patience. Every organization is giving up some autonomy for the benefit of the whole. While many traditions will remain, some will be eliminated. In addition, no matter how long and how hard we work towards the transition date, some glitches are likely to occur. While some of the services we provide may not be available in the beginning, they will be phased in during the first two years. We apologize for this ahead of time and pledge to do everything possible to exceed your highest expectations in this transition.

We hope that each and every pharmacist will see value in our professional, communications, legislative and education services. While health care is unpredictable these days, it is exciting for us to see pharmacists from every facet of the profession coming together to build a stronger profession.

Thank you for your support and advice.

| | | | |
|---|---|---|---|
| Kevin Almond<br>President<br>NCPhA | Bill Harris<br>President<br>NCSHP | Margaret Sgritta<br>President<br>NCASCP | Tim White<br>President<br>NCRPhA |

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# Senior PHARMAssist

## Pharmaceutical Care for Community-Dwelling Elderly with Low Incomes: The Durham Experience

*Author Gina Upchurch, RPh., MPH, reviews medications with a client.*

### by Gina Upchurch, RPh, MPH

Director, Durham Senior PHARM*Assist*

Senior PHARM*Assist* is a charitable, nonprofit pharmaceutical care program in Durham that educates older adults and their healthcare providers about safe and affordable medication use among the elderly. The program also helps many older adults pay for their medicines, including over 650 Durham County seniors since June 1994. Senior PHARM*Assist* is unique because it combines comprehensive one-on-one medication counseling and outcomes-based evaluation

*Continued from page 7*

with financial access to necessary medicines. While the nation has recently heard a lot about older adults who are struggling to pay for their medicines and about pharmacists being involved and being reimbursed for *cognitive services*, rarely are the two public health issues (financial access and pharmaceutical care) combined.

Senior PHARM*Assist* is a model for the state and nation that seeks to promote the wise use of medications in the elderly to help sustain their well being and independence. Senior PHARM*Assist* believes that medications, when used safely and effectively, are one of the most cost-effective preventive care tools we have. Senior PHARM*Assist's* self-evaluation provides a strong indicator of cost effective health care. After clients have been enrolled in the program one year, they have a third fewer ER visits and inpatient hospital stays.

### Who Pays for the Medicines for Medicare Recipients?

Senior citizens are the fastest growing segment of our population. People 65 years and older currently constitute 12.7% of the U.S. population, and this is expected to grow to approximately 20% of the population by the year 2030.[1] Although they comprise less than 13% of the population, they consume approximately 34% of prescription medications dispensed and 40% of all over-the-counter medications.[2,3] While Medicaid pays for outpatient medications, Medicare only covers a handful of chemotherapeutic agents and nebulizer medicines. In the last six months, the lack of prescription coverage for older adults in general, and with low incomes in particular, has been the topic of much wrangling in Washington. The Joint Commission on Medicare Reform disbanded in March and failed to make a formal recommendation to add prescription benefits for Medicare recipients.

While a national survey in 1995 demonstrated that roughly 65% of Medicare recipients have prescription benefits, many of the recipients do not have a clear idea of what their insurance actually covers. In addition, many of the prescription plans leave the older adult with limited coverage, and thus they are underinsured. Among the Medicare recipients living in the community, supplemental coverage includes many Medicare HMOs, Medicaid, VA benefits, employer-sponsored plans, individually purchased Medicare supplemental policies (H, I, or J), and twelve states have statewide pharmaceutical assistance programs for the elderly that reach beyond the Medicaid income guidelines. Medicare beneficiaries with no supplemental coverage are likely to have lower incomes than the average Medicare beneficiary.[4]

Adding a prescription benefit for Medicare recipients has been seriously discussed at the national level on several occasions, such as when the Medicare Catastrophic Act of 1988 and the 1993 Clinton plan for healthcare were debated. These plans were each defeated when the neediest were the only "benefactors." One of the biggest impediments to adding prescription benefits for all Medicare is that projected annual costs would be $20-40 billion.[5] In March 1999, Drs. Stephen Soumerai and Dennis Ross-Degnan, both of Harvard University proposed a national pharmaceutical care program to cover the "near-poor." In 1999, this plan would cost $4.1 billion, but financial *means testing* of Medicare benefits (basing benefits on income) does not have much political support. In addition, there is much opposition to the federal government getting involved in paying for medicines for fear of later price controls. In fact, the states operate the Medicaid programs even though federal dollars are the majority of what supports Medicaid prescription benefits.

### Financial Access for North Carolina's Elderly

In January, Medicaid in North Carolina expanded to help older adults with incomes up to 100% of the federal poverty level ($671/month). Before that time, an older adult had to have a monthly income below $494 to qualify for Medicaid and its prescription benefits. Many seniors with low incomes are not "poor enough" to qualify for Medicaid. Between 1981 and 1998, the rate of inflation for prescription drugs has increased at over 2.5 times the general rate of inflation.[6] While medication costs continue to climb, many older adults who depend solely on their social security income cannot pay out-of-pocket for several medications a month.

### More than Money

In addition to financial issues, the problem is compounded if they have several chronic health problems requiring multiple medications. Such a person often sees a variety of healthcare specialists, but none of them may have a complete picture of the medications (prescription and over-the-counter) that the patient may be taking. As a result, drug interactions and drug-induced illness are not uncommon. Also, medications often affect seniors differently than the general population which further raises the risk of adverse reactions. Problematic medication use among the elderly has costly healthcare implications, including unnecessary visits to hospital emergency rooms and admissions to hospitals, adult care homes, and nursing homes.

Senior PHARM*Assist* believes that access to medications alone is not the answer to our elderly's medication crisis. Medication access must be combined with the *safe and effective use* of medicines to help promote the health of older adults. With the barrage of direct to consumer advertising combined with the harried physician and community pharmacist encounters, Senior PHARM*Assist* has been able to facilitate appropriate medication use in the place of what could very likely be unnecessary, and even harmful, polypharmacy.

### How Does Senior PHARM*Assist* work and who is helped?

Although medication counseling is available to all Durham County seniors, eligibility for Senior PHARM*Assist* financial assistance is determined by income: seniors must be above the

*Continued on page 26*

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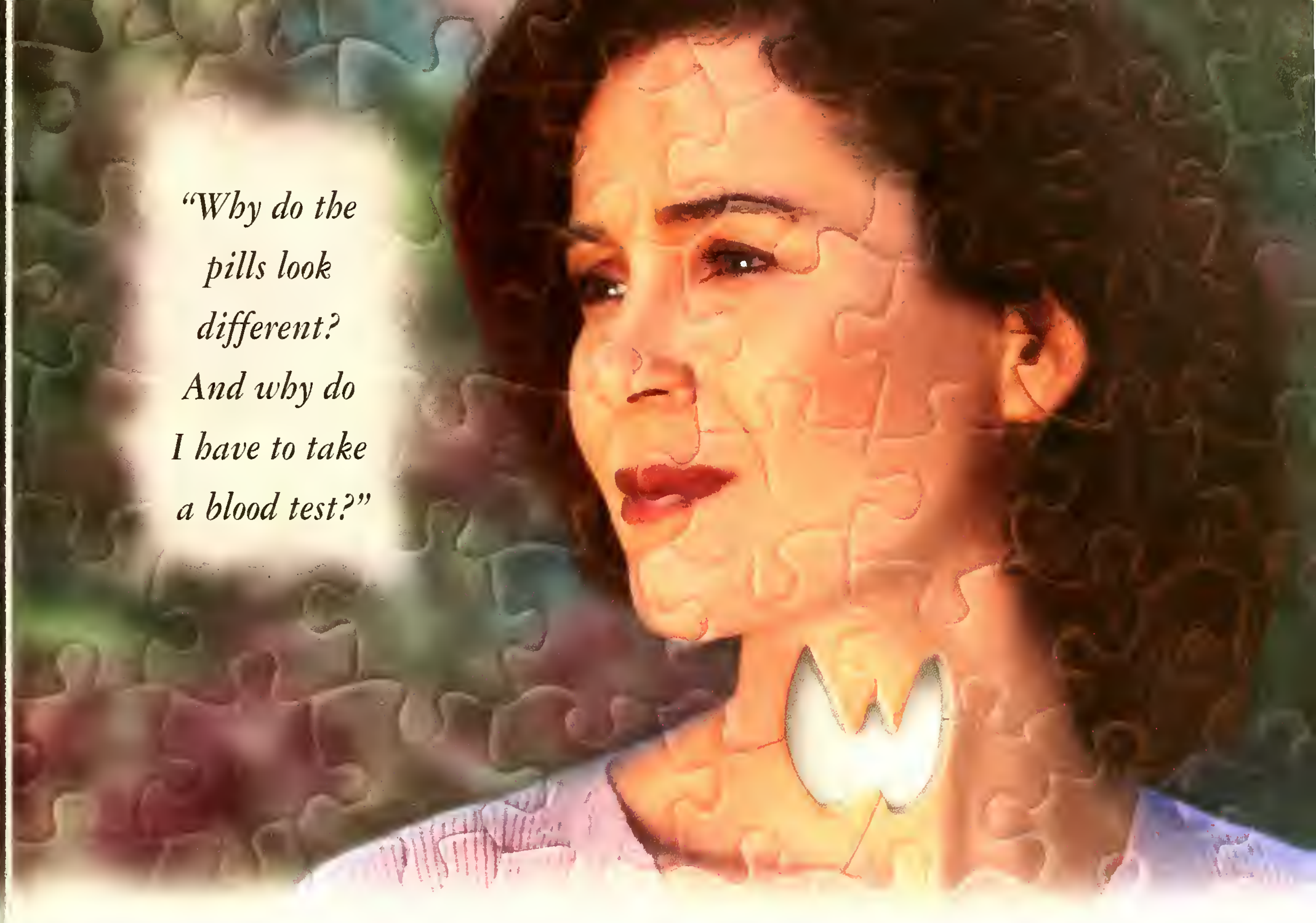
About the Author:

*Gina Upchurch is the Executive Director of Senior PHARMAssist in Durham, North Carolina. She has appointments as clinical assistance professor at the UNC School of Pharmacy and as Adjunct Instructor at the UNC School of Public Health. She also provides consulting to other communities that are developing pharmaceutical care services for underserved populations. She can be reached at (919) 688-4772.*



# Hormone replacement requires a precise fit: Is it worth switching her SYNTHROID?

**Substitution can require TSH testing and retitration**
Not to mention phone calls to physicians and questions from patients. And because there may be a change in TSH, the patient may need to be retitrated.

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(levothyroxine sodium tablets, USP)

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*Dose to dose.*
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Please see brief summary of prescribing information on adjacent page

*Average wholesale price per tablet as of 5/1/98 based on purchase of 100-tablet bottle of 100 mcg tablets. Source: Price-Chek PC ' Price History Report. © 1998 Medi-Span, Inc

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Printed in USA

Brief Summary (for full prescribing information see package circular.)

# SYNTHROID®

## (levothyroxine sodium, USP)

**SYNTHROID Tablets –** for oral administration
**SYNTHROID Injection –** for parenteral administration

**CONTRAINDICATIONS** SYNTHROID is contraindicated in patients with untreated thyrotoxicosis of any etiology or an apparent hypersensitivity to thyroid hormones or any of the inactive product constituents. (The 50 mcg tablet is formulated without color additives for patients who are sensitive to dyes.) There is no well-documented evidence of true allergic or idiosyncratic reactions to thyroid hormone SYNTHROID is also contraindicated in the patients with uncorrected adrenal insufficiency, as thyroid hormones increase tissue demands for adrenocortical hormones and may thereby precipitate acute adrenal crisis (see **PRECAUTIONS**)

**WARNINGS** Thyroid hormones, either alone or together with other therapeutic agents, should not be used for the treatment of obesity In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

The use of SYNTHROID in the treatment of obesity, either alone or in combination with other drugs, is unjustified The use of SYNTHROID is also unjustified in the treatment of male or female infertility unless this condition is associated with hypothyroidism.

**PRECAUTIONS General** SYNTHROID should be used with caution in patients with cardiovascular disorders, including angina, coronary artery disease, and hypertension, and in the elderly who have a greater likelihood of occult cardiac disease. Concomitant administration of thyroid hormone and sympathomimetic agents to patients with coronary artery disease may increase the risk of coronary insufficiency

Use of SYNTHROID in patients with concomitant diabetes mellitus, diabetes insipidus or adrenal cortical insufficiency may aggravate the intensity of their symptoms. Appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine diseases may therefore be required. Treatment of myxedema coma may require simultaneous administration of glucocorticoids (see **DOSAGE AND ADMINISTRATION**).

$T_4$ enhances the response to anticoagulant therapy. Prothrombin time should be closely monitored in patients taking both SYNTHROID and oral anticoagulants, and the dosage of anticoagulant adjusted accordingly.

Seizures have been reported rarely in association with the initiation of levothyroxine sodium therapy, and may be related to the effect of thyroid hormone on seizure threshold.

Lithium blocks the TSH-mediated release of $T_4$ and $T_3$. Thyroid function should therefore be carefully monitored during lithium initiation, stabilization, and maintenance. If hypothyroidism occurs during lithium treatment, a higher than usual SYNTHROID dose may be required.

**Laboratory Tests** Treatment of patients with SYNTHROID requires periodic assessment of adequacy of titration by appropriate laboratory tests and clinical evaluation. Selection of appropriate tests for the diagnosis and management of thyroid disorders depends on patient variables such as presenting signs and symptoms, pregnancy, and concomitant medications. A combination of sensitive TSH assay and free $T_4$ estimate (free $T_4$, free $T_4$ index) are recommended to confirm a diagnosis of thyroid disease. Normal ranges for these parameters are age-specific in newborns and younger children.

TSH alone or initially may be useful for thyroid disease screening and for monitoring therapy for primary hypothyroidism as a linear inverse correlation exists between serum TSH and free $T_4$ Measurement of total serum $T_4$ and $T_3$, resin $T_3$ uptake, and free $T_3$ concentrations may also be useful. Antithyroid microsomal antibodies are an indicator of autoimmune thyroid disease The presence of positive microsomal antibodies in an euthyroid patient is a major risk factor for the future development of hypothyroidism. An elevated serum TSH in the presence of a normal $T_4$ may indicate subclinical hypothyroidism. Intracellular resistance to thyroid hormone is quite rare, and is suggested by clinical signs and symptoms of hypothyroidism in the presence of high serum $T_4$ levels. Adequacy of SYNTHROID therapy for hypothyroidism of pituitary or hypothalamic origin should be assessed by measuring free $T_4$, which should be maintained in the upper half of the normal range. Measurement of TSH is not a reliable indicator of response to therapy for this condition. Adequacy of SYNTHROID therapy for congenital and acquired pediatric hypothyroidism should be assessed by measuring serum total $T_4$ or free $T_4$, which should be maintained in the upper half of the normal range. In congenital hypothyroidism, normalization of serum TSH levels may lag behind normalization of serum $T_4$ levels by 2 to 3 months or longer In rare patients serum TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of $T_4$ or free $T_4$.

**Drug Interactions** The magnitude and relative clinical importance of the effects noted below are likely to be patient-specific and may vary by such factors as age, gender, race, intercurrent illnesses, dose of either agent, additional concomitant medications, and timing of drug administration. Any agent that alters thyroid hormone synthesis, secretion, distribution, effect on target tissues, metabolism, or elimination may alter the optimal therapeutic dose of SYNTHROID.

*Adrenocorticoids*–Metabolic clearance of adrenocorticoids is decreased in hypothyroid patients and increased in hyperthyroid patients, and may therefore change with changing thyroid status.

*Amiodarone*–Amiodarone therapy alone can cause hypothyroidism or hyperthyroidism.

*Anticoagulants (oral)*–The hypoprothrombinemic effect of anticoagulants may be potentiated, apparently by increased catabolism of vitamin K-dependent clotting factors.

*Antidiabetic agents (insulin, sulfonylureas)*–Requirements for insulin or oral antidiabetic agents may be reduced in hypothyroid patients with diabetes mellitus, and may subsequently increase with the initiation of thyroid hormone replacement therapy

*β-adrenergic blocking agents*–Actions of some beta-blocking agents may be impaired when hypothyroid patients become euthyroid.

*Cytokines (interferon, interleukin)*–Cytokines have been reported to induce both hyperthyroidism and hypothyroidism

*Digitalis glycosides*–Therapeutic effects of digitalis glycosides may be reduced. Serum digitalis levels may be decreased in hyperthyroidism or when a hypothyroid patient becomes euthyroid.

*Ketamine*–Marked hypertension and tachycardia have been reported in association with concomitant administration of levothyroxine sodium and ketamine.

*Maprotiline*–Risk of cardiac arrhythmias may increase

*Sodium iodide ($^{123}I$ and $^{131}I$), sodium pertechnetate Tc99m*–Uptake of radiolabeled ions may be decreased.

*Somatrem/somatropin*—Excessive concurrent use of thyroid hormone may accelerate epiphyseal closure. Untreated hypothyroidism may interfere with the growth response to somatrem or somatropin.

*Theophylline*—Theophylline clearance may decrease in hypothyroid patients and return toward normal when a euthyroid state is achieved.

*Tricyclic antidepressants*—Concurrent use may increase the therapeutic and toxic effects of both drugs, possibly due to increased catecholamine sensitivity Onset of action of tricyclics may be accelerated.

*Sympathomimetic agents*—Possible increased risk of coronary insufficiency in patients with coronary artery disease.

**Laboratory Test Interactions** A number of drugs or moieties are known to alter serum levels of TSH, $T_4$ and $T_3$ and may thereby influence the interpretation of laboratory tests of thyroid function (see **Drug Interactions**).

1. Changes in TBG concentration should be taken into consideration when interpreting $T_4$ and $T_3$ values. Drugs such as estrogens and estrogen-containing oral contraceptives increase TBG concentrations. TBG concentrations may also be increased during pregnancy and in infectious hepatitis. Decreases in TBG concentrations are observed in nephrosis, acromegaly, and after androgen or corticosteroid therapy Familial hyper- or hypo-thyroxine-binding-globulinemias have been described. The incidence of TBG deficiency is approximately 1 in 9000. Certain drugs such as salicylates inhibit the protein-binding of $T_4$. In such cases, the unbound (free) hormone should be measured. Alternatively, an indirect measure of free thyroxine, such as the $FT_4I$ may be used

2 Medicinal or dietary iodine interferes with *in vivo* tests of radioiodine uptake, producing low uptakes which may not indicate a true decrease in hormone synthesis.

3. Persistent clinical and laboratory evidence of hypothyroidism despite an adequate replacement dose suggests either poor patient compliance, impaired absorption, drug interactions, or decreased potency of the preparation due to improper storage.

**Carcinogenesis, Mutagenesis, and Impairment of Fertility:** Although animal studies to determine the mutagenic or carcinogenic potential of thyroid hormones have not been performed, synthetic $T_4$ is identical to that produced by the human thyroid gland.

A reported association between prolonged thyroid hormone therapy and breast cancer has not been confirmed and patients receiving levothyroxine sodium for established indications should not discontinue therapy

**Pregnancy:** Pregnancy Category A. Studies in pregnant women have not shown that levothyroxine sodium increases the risk of fetal abnormalities if administered during pregnancy. If levothyroxine sodium is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, levothyroxine sodium should be used during pregnancy only if clearly needed.

Thyroid hormones cross the placental barrier to some extent. $T_4$ levels in the cord blood of athyroid fetuses have been shown to be about one-third of maternal levels. Nevertheless, maternal-fetal transfer of $T_4$ may not prevent *in utero* hypothyroidism.

Hypothyroidism during pregnancy is associated with a higher rate of complications, including spontaneous abortion and preeclampsia, and has been reported to have an adverse effect on fetal and childhood development On the basis of current knowledge, SYNTHROID® (levothyroxine sodium, USP) should therefore not be discontinued during pregnancy and hypothyroidism diagnosed during pregnancy should be treated Studies have shown that during pregnancy $T_4$ concentrations may decrease and TSH concentrations may increase to values outside normal ranges. Postpartum values are similar to preconception values. Elevations in TSH may occur as early as 4 weeks gestation.

Pregnant women who are maintained on SYNTHROID should have their TSH measured periodically An elevated TSH should be corrected by an increase in SYNTHROID dose After pregnancy, the dose can be decreased to the optimal preconception dose.

**Nursing Mothers** Minimal amounts of thyroid hormones are excreted in human milk. Thyroid hormones are not associated with serious adverse reactions and do not have known tumorigenic potential. While caution should be exercised when SYNTHROID is administered to a nursing woman, adequate replacement doses of levothyroxine sodium are generally needed to maintain normal lactation.

**Pediatric Use: Congenital hypothyroidism**. Rapid restoration of normal serum $T_4$ concentrations is essential for preventing the deleterious effects of neonatal thyroid hormone deficiency on intelligence, as well as on overall growth and development. SYNTHROID should be initiated immediately upon diagnosis, and is generally continued for life. The goal of therapy is to maintain the serum total $T_4$ or $FT_4$ in the upper half of the normal range and serum TSH in the normal range.

An initial starting dose of 10 to 15 mcg/kg/day (ages 0-3 months) will generally increase serum $T_4$ concentrations to the upper half of the normal range in less than 3 weeks. Clinical assessment of growth and development and thyroid status should be monitored frequently In most cases, the dose of SYNTHROID per body weight will decrease gradually as the patient grows through infancy and childhood (see Table). Prolonged use of large doses in infants may be associated with later behavior problems.

Thyroid function tests (serum total $T_4$ or $FT_4$, and TSH) should be monitored closely and used to determine the adequacy of SYNTHROID therapy Normalization of serum $T_4$ levels is usually followed by a rapid decline of TSH levels. Nevertheless, normalization of TSH may lag behind normalization of $T_4$ levels by 2 to 3 months or longer. The relative elevation of serum TSH is more marked during the early months of therapy, but can persist to some degree throughout life. In rare patients TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of total $T_4$ or $FT_4$ Increasing the SYNTHROID dosage to suppress TSH into the normal range may result in overtreatment, with an elevated serum $T_4$ level and clinical features of hyperthyroidism, including irritability, increased appetite with diarrhea and sleeplessness. Another risk of prolonged overtreatment in infants is premature cranial synostosis.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected Levothyroxine therapy may be interrupted for 30 days after 3 years of age and serum measurement of T4 and TSH levels obtained. If $T_4$ is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted If $T_4$ and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted

**Acquired hypothyroidism.** The initial dose of SYNTHROID varies with age and body weight, and should be adjusted to maintain serum total $T_4$ or free $T_4$ levels in the upper half of the normal range. In general, in the absence of overriding clinical concerns, children should be started on a full replacement dose. Children with underlying heart disease should be started at lower doses, with careful upward titration. Children with severe, long-standing hypothyroidism may also be started on a lower initial dose with upward titration in an attempt to avoid premature closure of epiphyses. The recommended dose per body weight decreases with age (see Table).

Treated children may resume growth at a rate greater than normal (period of transient catch-up growth). In some cases catch-up growth may be adequate to normalize growth; however, in children with severe and prolonged hypothyroidism, adult height may be reduced. Excessive thyroxine replacement may initiate accelerated bone maturation resulting in disproportionate advancement in skeletal age and shortened adult stature.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected. Levothyroxine therapy may be interrupted for 30 days and serum measurement of $T_4$ and TSH levels obtained If $T_4$ is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted. If $T_4$ and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted.

**ADVERSE REACTIONS**. Adverse reactions other than those indicative of thyrotoxicosis as a result of therapeutic overdosage, either initially or during the maintenance periods, are rare (see **OVERDOSAGE**). Craniosynostosis has been associated with iatrogenic hyperthyroidism in infants receiving thyroid hormone replacement therapy Inadequate doses of SYNTHROID may produce or fail to resolve symptoms of hypothyroidism. Hypersensitivity reactions to the product excipients, such as rash and urticaria, may occur Partial hair loss may occur during the initial months of therapy, but is generally transient. The incidence of continued hair loss is unknown. Pseudotumor cerebri has been reported in pediatric patients receiving thyroid hormone replacement therapy

**OVERDOSAGE: Signs and Symptoms:** Excessive doses of SYNTHROID result in a hypermetabolic state indistinguishable from thyrotoxicosis of endogenous origin. Signs and symptoms of thyrotoxicosis include weight loss, increased appetite, palpitations, nervousness, diarrhea, abdominal cramps, sweating, tachycardia, increased pulse and blood pressure, cardiac arrhythmias, tremors, insomnia, heat intolerance, fever, and menstrual irregularities Symptoms are not always evident or may not appear until several days after ingestion.

**CAUTION** Federal (USA) law prohibits dispensing without a prescription.

See Full Prescribing Information.

Tablets Manufactured by
BASF Pharmaceuticals
A Unit of BASF
Jayuya, Puerto Rico 00664

Injection Manufactured by
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For
Knoll Pharmaceutical Company

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Issued April 21, 1997

SYN-0497-142

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BASF Pharma

# WARD DRUG COMPANY

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Phone: (252) 459-2135 or (800) 721-5701
FAX: (252) 459-9300 or (800) 572-1056
E-mail: glisson@warddrug.com

Manager: Gary Glisson, RPh, F.A.C.A.

Education: BS in Pharmacy from UNC Chapel Hill
PCCA Certified Compounding Pharmacist

### Describe your overall practice.

Ward Drug Company is a unique, niche-marketed pharmacy that caters to individualizing patient care and customizing medications to fit patient-specific needs.

### What unique services do you provide?

The **Diabetic Shoppe**, which offers Medicare covered Diabetic Extra Depth Shoes; blood glucose testing; blood glucose monitor training, cleaning, and calibration; a complete selection of diabetic supplies; a large selection of sugar-free foods and products; a diabetic support group; and a free quarterly diabetic newsletter.

At our **Customized Prescription Compounding Lab** with PCCA Membership, we can individualize medications for both humans and animals, flavor any liquid medication, provide unique dosage forms, and eliminate sugars, dyes, preservations and allergens.

The **Wellness Store**...a natural pharmacy, provides individualized custom compounded nutritional/herbal dosage forms, pharmaceutical grade herbal and nutritional products, and private nutritional consultations.

We offer **Customized Natural Hormone Replacement Therapy** (HRT) so we can team with a physician to naturally restore a woman's hormone levels during and after menopause. Ward Drug compounds various hormone products in a variety of dosage forms. These forms include transdermal or transmucosal dosage forms such as gels, troches, or suppositories, capsules containing micronized particles for enhanced oral absorption, and many others.

The **DynaPulse Blood Pressure Club**, which uses the DynaPulse computer-based blood pressure and cardiovascular monitoring system. With it, we can view clinical-grade blood pressure and cardiovascular measurements; see a display of each patient's own pulse waveforms to study heartbeat and validate measurements; monitor the long-term effects of factors that can affect measurements such as diet, exercise, and hypertensive medications; obtain a lifetime of DynaPulse measurements in the patient's individualized computer record; and distribute color print-outs of each measurement to the consenting patient's physician.

The **Cholestech LDX® System**, an advanced personalized cholesterol monitoring machine that can determine a patient's blood cholesterol level in five minutes. Patients can be screened for total cholesterol, total cholesterol and HDL, total cholesterol, HDL and Glucose, or a full lipid panel and glucose. We can then perform a cardiac risk assessment on each patient and provide professional diet and exercise counseling.

*Pharmacist Gary Glisson offers unique services to his patients.*

An **Asthma & Allergy Management Program** with a large selection of asthma and allergy products to meet the individual patient's needs. We also offer counseling on each product, including nebulizers, peak flow meters and spacer/holding chamber instruction.

We carry **Maddox Oncology Products**, a line of products developed by a breast cancer survivor to help other survivors cope with the adverse effects of chemotherapy or radiation treatment.

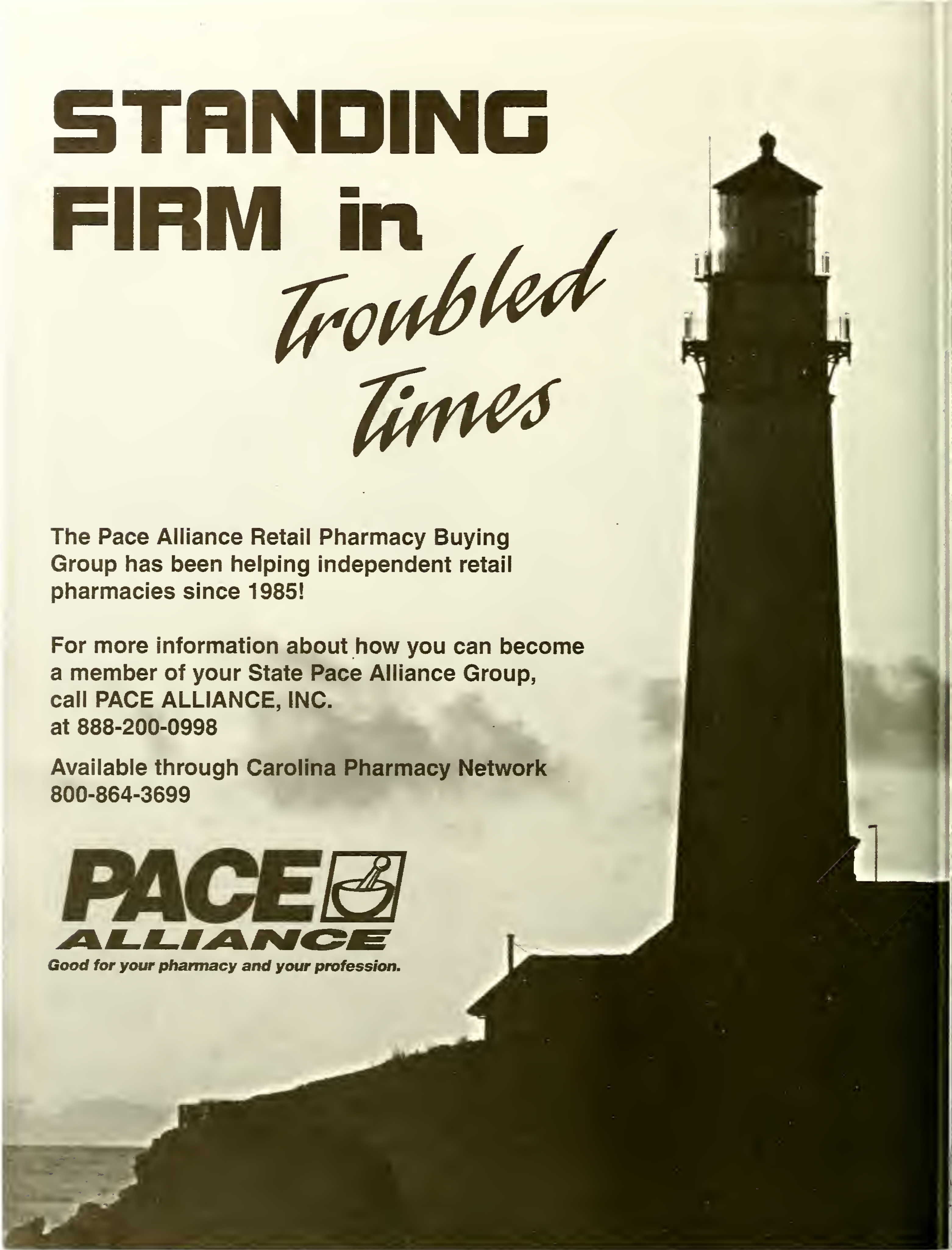
The **Floral Expressions and Thinking of You Gift Shoppe**, with a full service florist is located right in the store. Ward Drug is also a member of the Teleflora and AFS groups. We also offer gift baskets with "NC Home Grown" specialty items, floral and balloons for wedding receptions and special events, tuxedo rentals, and worldwide shipping.

### How did you determine the need for these services? How did you develop your practice to meet those needs?

At a 1992 National Meeting, a talk on the DCCT addressed the issue of catering to the needs of the diabetic population. I predicted this to be a major issue, so I designed my store accordingly.

In regards to compounding, someone needed to provide

*Continued on page 28*



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# FASTER, BETTER COMMUNICATION?

## *Patient Care Insight Communication Software*

by Sandra G. Jue, Pharm.D., FASHP

> *You greet a new customer and ask the routine questions. As you start to go over the use of the medicine and its side effects, you sense that the patient does not seem to believe what you are saying. There is a long line of customers, so you hurry through the counseling. The patient asks how much and disappears towards the registers in another part of the store. Did you have the feeling that he did not trust you? Did you have the feeling that the patient might not comply with the directions? Will you ever see the patient again to check what your instincts and experience told you?*

A new product may be able to help — HealthCare Insights. Created by the Hall Group of Raleigh, North Carolina, the Insights software installs from a CD-ROM and requires about 3.6 MB of space on your hard drive.[1] It runs under Windows 95 and Windows NT. Even novice computer users can install this. It is simple to use this instrument even in a busy community store, as demonstrated in the Asheville Project, for which this instrument was designed.[2]

The patient completes a one-page instrument during the time it takes to fill his prescription (about five minutes). A technician or pharmacist scores the communication tool in a few minutes using the software installed on a standard PC. The results are printed on one page and are simple to understand. The patient's basic style is stated as four adjectives. Here is a sample of our 38-year-old man:

```
    This Communication Insight has been
developed expressly for Joe Smith.

His basic style is:
• Friendly
• Deliberate
• Precise
• Conservative.

    The patient is not a high risk-taker. He
will want to know all details and consequences
of recommended procedures and treatments. He
may be slow to respond and make decisions because
of hesitancy to act without complete information
and understanding of risks involved.

To increase trust and compliance:
• Take time to fully explain diagnosis and
treatment plan.
• Allow time for him to think about options
(if any), but not procrastinate.
• Take control of plan and instruct him precisely
about action he must take.
• Whenever possible, provide a detailed written
plan.
• Accurate and complete information is key to
his cooperation.
```

We have found the information to be highly accurate. Of more than 100 such surveys, the subjects found them to characterize their style with more than 80% accuracy. Even more interesting is that the style revealed in the survey seems to represent how the subject feels at the moment. Under stress, we found some of the subjects change styles. We would like to study how often stresses can change subjects' styles.

I have used the results of the surveys in my clerkship teaching. I have altered my approach to individual students using the knowledge about their basic style. It has increased my personal satisfaction and expectations about each student.

I also gave the survey to my administrator. After reading the basic style of my administrator, I understood why my last proposal was rejected. I think I know how to present the next proposal to appeal to his basic style now. Surprisingly, none of these individuals objected. Most were flattered with their results and happy to help me validate the instrument.

Another use for the survey was applied to patients who were enrolled in a hospital program which had a 50% cut back in funding. Rather than arbitrarily cut patients, the administrator decided to give the survey to patients who were not complying with their treatment plans. She would alter the approach to these patients based on their basic style. If they were still not complying with their treatment, they would be dropped from the program. I think it was novel to see a scientific basis for dropping patients from a program.

This tool gives insight into the basic style of everyone we communicate with. It could be especially helpful in shortening the time to discover how a particular patient behaves. We can then use our time more effectively. The 16 seconds[3] spent counseling could be directed to the most useful ways that gain trust and increase compliance. ◉

Notes:

[1] Health Care Insights, The Hall Group, 1381 Kildaire Farm Road #411, Cary, North Carolina 27511-5525.

[2] Garrett DG. The answer to how is when: the genesis of the Asheville project. *Pharmacy Times* Supplement, October 1998, pp 4-5.

[3] Anon. Counseling Survey. *Idaho Board of Pharmacy Newsletter* (Sept) 1997; 17:1.

About the Author: *Sandra G. Jue, Pharm.D., FASHP is the Clinical Pharmacy Teaching Coordinator at the Veterans Affairs Medical Center in Boise, Idaho. She is also Clinical Professor of Pharmacy Practice at Idaho State University College of Pharmacy, Pocatello, Idaho. She teaches long-term care to fourth-year pharmacy students in the doctor of pharmacy program. She precepts one of the first ASHP-accredited geriatric pharmacy residencies in the nation. Her research interests include patient compliance and reimbursement for pharmaceutical care management.*

Insight software is co-marketed by the Hall Group and NCAP. For more information on this software, please write brent@ncpharmacists.org or call Brent Spodek at (800) 852-7343.

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# PAVING THE WAY TO PHARMACEUTICAL CARE
## An Update on the Asheville Project

by Beth S. Williams, PharmD

Two years ago, a group of dedicated individuals within the Asheville community gave each of us a priceless gift. Most of us did not realize it at the time, but those who unselfishly committed to participate in this collaborative diabetes care demonstration project paved the way for pharmacists across the state, and perhaps the country, to transition into a true pharmaceutical care role. Much has happened since March 1997.

By now, many of you are familiar with the Asheville Project - the demonstration project which proved the value of pharmaceutical care in terms of lowered health care costs, improved clinical outcomes, improved patient satisfaction, improved absenteeism, and professional enhancement. It has attracted national as well as international interest, not only from our professional colleagues, but from third-party payers and employers as well. In fact, rarely a day goes by that NCCPC does not receive an inquiry about the Asheville Project. From Miami to Indiana, pharmacists from across the country want to know how to replicate the Asheville Project in their communities.

Just eight months after the inception of the Asheville Project, it began receiving significant press and recognition on both local and national levels. Written attention has been varied and widespread, from the *Asheville Citizen Times* to *Pharmacy Times*, from the *American Journal of Health-System Pharmacy* to *Business Insurance*. John Miall, Risk Manager for the City of Asheville, has become one of the most sought after non-pharmacists on our profession's speaker's bureau. He has spoken of this most innovative collaborative effort on the national level, at meetings of the American Pharmaceutical Association (APhA) and the American College of Clinical Pharmacists (ACCP); and on the State level, to audiences in Georgia, North Carolina, Ohio, and Virginia. In addition, Miall has been a guest speaker at several meetings sponsored by Parke-Davis to introduce the program to major employers and insurers around the country, including Ford, GM, Chrysler, GTE, and Intel. Currently, the Asheville Project is a semi-finalist for the 1999 Harvard Award for Innovations in American Government in the area of Health and Human Services. To Miall, this prestigious award is his "Nobel Prize." However, this is not the first award that the Asheville Project has received. In March of this year, the North Carolina Chapter of the International Personnel Management Association (IPMA) named the Asheville Project its 1999 Innovation Award winner in the area of Employee Benefits, Safety and Risk Management. Miall has definitely made a name for himself, the City of Asheville, and collaborative practice in North Carolina. Our profession owes this risk-taker enormous gratitude for helping to get the word out about the value of pharmaceutical care.

**...with time, pharmaceutical care will be the expectation, not the exception**

On the local front, the Asheville Project now encompasses asthma care and plans to offer hypertension care to City employees in the near future. In addition, beginning in March 1999, the Mission + St. Joseph's Health System in Asheville began offering pharmaceutical care in the areas of diabetes and asthma as an employee health benefit. In order to meet the demands of the Asheville Project, the number of pharmacist-providers has doubled from its original fifteen and now includes chain pharmacists.

*Pharmacist Ruth Higgins discusses diabetes with an Asheville city employee.*

On the state level, NCAP and the North Carolina Center for Pharmaceutical Care (NCCPC) have committed to efforts to replicate the Asheville Project in up to ten North Carolina communities. With the support of Glaxo Wellcome, Inc., NCCPC is funding NCAP's efforts. Glaxo Wellcome, Inc. is funding the development of practice tools and community initiatives to facilitate these local efforts. Potential sites for the replication of the Asheville Project include the following North Carolina communities:

- Lumberton
- Greensboro
- Wilson/Nashville
- Erwin
- New Bern
- Greenville
- Raeford
- Elkin
- Raleigh/Durham
- Wilmington
- Goldsboro
- Gastonia
- North Wilkesboro
- Concord

If you would like to take part in one of the above local efforts, or if you would like more information about how to replicate the Asheville Project, please call Beth Williams at NCAP. If you would simply like more information about the Asheville Project, please refer to the October 1998 issue of *Pharmacy Times* or call NCAP at (800) 852-7343.

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# COX-2 INHIBITORS

by Heather C. Whitaker, Pharm.D. Candidate,
Campbell University School of Pharmacy

and Michelle A. Long, Pharm.D., Drug Information Resident
Campbell University School of Pharmacy

Selective cyclooxygenase-2 (COX-2) inhibitors are a new class of medications available for the treatment of osteoarthritis and rheumatoid arthritis which affects a combined total of 22.8 million Americans.[1] These agents provide analgesic and anti-inflammatory properties with a more favorable side effect profile than traditional nonsteroidal anti-inflammatory drugs (NSAIDs).[2,3] Celecoxib (Celebrex®- Searle) is the first COX-2 inhibitor approved by the FDA and is currently available by prescription.

Conventional NSAIDs inhibit COX-1, COX-2, and thromboxane synthesis. Located in the gastric mucosa, COX-1 synthesizes prostaglandins, reduces gastric acid secretion, and stimulates gastric mucosa production. Inhibition of COX-1 is thought to be responsible for NSAID-induced gastropathy which causes 16,500 deaths and 107,000 hospitalizations annually.[4] Furthermore, inhibition of COX-1 interferes with thromboxane-induced platelet aggregation thus increasing bleeding tendency.

Selective COX-2 inhibitors inhibit the inducible form of cyclooxygenase which is primarily responsible for pain and inflammation. Although COX-2 inhibitors do not inhibit COX-1 at therapeutic doses, the risk of NSAID-induced ulceration is still present. According to data from a randomized, double-blind, six-month study in 430 rheumatoid arthritis patients, celecoxib 200 mg twice daily caused endoscopic ulceration in 4% of patients compared to 15% of patients treated with diclofenac 75 mg twice daily ($p<0.001$).[5] In another twelve-week study of 1062 patients with osteoarthritis or rheumatoid arthritis, celecoxib 200 mg twice daily caused a 7% incidence of gastroduodenal ulcers compared to a 23.3% incidence in patients treated with ibuprofen 800 mg three times daily ($p<0.05$).[5] Until additional studies reveal that celecoxib has a safer gastric profile, the FDA will require that celecoxib labeling have the standard NSAID class warning which includes an estimate of the risk of GI ulceration, bleeding, or perforation associated with celecoxib.[6]

Celecoxib is rapidly absorbed and may be taken without regard to meals. It is metabolized by the cytochrome P450 2C9 enzyme system which causes the potential for interactions with medications that induce or inhibit this enzyme. Cytochrome P450 2C9 inhibitors such as zafirlukast, fluconazole, fluvastatin, and amiodarone may increase celecoxib concentrations. Likewise, celecoxib may inhibit the metabolism of medications metabolized by the 2D6 enzyme system, such as some antidepressants, antipsychotics, and beta-blockers. Celecoxib does not alter the anticoagulant effect of warfarin. Similar to traditional NSAIDs, celecoxib may alter the antihypertensive properties of angiotensin-converting enzyme (ACE) inhibitors. Also, lithium concentrations may increase during celecoxib therapy.[5]

The recommended dose of celecoxib is 100 mg twice daily or 200 mg daily for osteoarthritis and 200 mg twice daily for rheumatoid arthritis. The safety and efficacy of celecoxib has not been determined in patients less than 18 years of age. Furthermore, celecoxib is contraindicated in patients with NSAID, aspirin, or sulfa hypersensitivity. Although classified as pregnancy category C, celecoxib should be avoided in late pregnancy as premature closure of the ductus arteriosus may occur.[5]

Abdominal pain, diarrhea, and dyspepsia are the most common adverse effects associated with celecoxib therapy. However, according to a recent article in *The Wall Street Journal*, celecoxib has been linked to ten deaths and eleven cases of GI hemorrage.[7] Considering that greater than 2.5 million prescriptions have been written for celecoxib, the FDA issued a statement that there is no evidence to suggest a relationship between death or hospitalization and the use of celecoxib.[8]

To date, there have been 40 documented potential and actual medication errors with celecoxib (Celebrex™) during its first two months on the market. Most of the errors documented were due to the substitution of medications with similar names. Celexa™ (citalopram, an antidepressant) and Cerebyx® (fosphenytoin, an anticonvulsant) were most frequently dispensed for Celebrex prescriptions. In a recent error, an 80-year-old woman had a Celebrex™ prescription filled with Celexa™ 20 mg tablets. She took the incorrect medication for approximately one month at which time she sought therapy from an acupuncturist for her unrelieved arthritic pain. Furthermore, the patient was concurrently taking venlafaxine, an antidepressant which increases serotonin concentration in the brain. Although the patient did not experience any adverse events, serotonin syndrome, a potentially fatal condition, has been reported in patients receiving two serotonerigic agents simultaneously. The Institute for Safe Medication Practices recently commissioned the manufacturer and the FDA to consider a brand name change for celecoxib.[9]

Celecoxib's place in therapy for the treatment of osteoarthritis and rheumatoid arthritis is still being defined. Healthcare practitioners should consider celecoxib as first line therapy for the elderly, alcoholics, patients with a previously documented ulcer, or patients receiving medications which increase the risk of bleeding such as aspirin, NSAIDs, and warfarin. However, the cost of celecoxib precludes its use as a first line agent for all patients. Celecoxib is $1.43 (100 mg) and $2.42 (200 mg) per capsule which is comparable to other brand-name NSAIDs but is significantly more expensive than generic ibuprofen.[6] Although celecoxib is as effective as traditional NSAID for the treatment of osteoarthritis and rheumatoid arthritis, long-term side effects are not known.

***Continued on page 28***

## UNC Announces Burrus Award Winners

The University of North Carolina School of Pharmacy is pleased to announce that third-year pharmacy student Amy Hatfield and class of 1938 alumnus James Creech and his wife, Vivia, are the inaugural winners of the Samuel B. Burrus Family Award for Community Service. The Award is a dual one, to be presented annually to members of the UNC School of Pharmacy family who exhibit "outstanding and unselfish civic, community, and/or church volunteer service provided outside the scope of regular pharmacy practice." One award is presented to a student currently enrolled in the School of Pharmacy. The second is awarded to an alumnus of the School, or to a husband and wife team, at least one of whom is an alumnus. Recipients receive a monetary award, a monetary award for their charity-of-choice, and a plaque noting their accomplishment. A permanent plaque to be displayed in the lobby of the School of Pharmacy will also list recipients on an annual basis.

This year's winners have gone above and beyond the call of duty in offering their time and talents to serve their communities. They participate in numerous service programs through their churches, professional and student organizations, and nonprofit groups. Amy Hatfield and Jimmy and Vivia Creech have set a high standard for future Burrus Award recipients to meet, and we congratulate them on their accomplishments.

Student nominees for the Burrus Award may be nominated by fellow students or by School of Pharmacy faculty or staff. Alumni must be nominated for the award by other UNC School of Pharmacy alumni. If you are an alumnus and know someone who is deserving of this award, please forward their name and supporting information to the Office of Advancement, UNC School of Pharmacy, CB# 7360 Beard Hall, Chapel Hill, NC 27599-7360. Nominations are accepted year-round.

## Joint UNC/Kerr Project Underway

At the Enhanced Pharmaceutical Care Center, patients are more than numbers, and pharmacists do more than fill prescriptions.

The newly founded center, located in Kerr Drug store at University Mall and co-sponsored by the University of North Carolina at Chapel Hill School of Pharmacy and Kerr Drug stores, is pioneering "pharmaceutical care" — the concept that pharmacists should establish individual relationships with patients and take responsibility for their care.

"Pharmaceutical care was simply a call to action for pharmacists to better care for their patients," said Rebecca Chater, site coordinator.

"It means not just dispensing pills but taking responsibility for the outcome of drug therapy and working collaboratively with other members of the health care team to better care for patients," she said.

For patients with long-term or chronic health problems, center pharmacists help monitor illnesses. For patients who take several medications, they explain the drugs' proper dosages and expected effects. For others, they offer blood pressure checks, bone-density and glaucoma tests and a variety of other screenings.

"All of these services come about from that philosophy of pharmacists taking responsibility for patient care," said Kim Deloatch, a clinical assistant professor at UNC who coordinates the care project for the pharmacy school.

"The primary goal of our curriculum is to prepare pharmacists to do more than traditional dispensing," she said. "That philosophy and that goal are a little bit ahead of where practice is. For us, the care center demonstrates to students that that kind of practice can, in fact, occur."

The center is staffed 20 hours weekly by Kerr Drug pharmacists and another 20 hours by UNC pharmacy school faculty members. Pharmacy school students also volunteer in the center.

Elaine Chin, a first-year pharmacy student from Charlotte, said she helps out at the center because she believes in its concept.

"As health providers, we should be health educators, as well," she said. "Patients need to be aware and informed about their medications. They need to know what their drugs do and how they can best optimize their therapy."

The center opened last September in a suite of offices within the drugstore. Since then, pharmacists and students have seen 400 patients. It has a waiting area, two private offices and a training room.

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# CREATION OF A PHARMACEUTICAL IPA:
## THE GREENSBORO EXPERIENCE

by Christopher Rubino, Pharm.D.

About a year and a half ago, a group of pharmacists from Greensboro formed the Greensboro Volunteer Pharmacists Taskforce to advance the practice of pharmacy in our community. That taskforce decided their first step would be to create a business entity which would encourage utilization and reimbursement of pharmacists for provision of clinical pharmacy services. On February 17, 1999, that business entity was incorporated as an independent provider association named Piedmont Pharmaceutical Care Network, L.L.C. (PPCN).

The thirty or so individuals who came together to form the Volunteer Pharmacists Taskforce were a diverse group of dedicated pharmacists. There were representatives from all areas of pharmacy in North Carolina – community (both independent and chain), hospital, long-term care/consulting, public health, education, and industry. One group of volunteers developed a business plan and investigated possible organizational structures. Another group began to discuss ways of developing pharmacist providers as well as certifying the credentials of those providers. A third group discussed potential technology issues. After several meetings with an attorney experienced in health care, the committee decided to designate a smaller group that would incorporate the IPA. This group of ten became the corporation's first Board of Directors. Some of the Board's tasks were to retain an attorney, create an operating agreement, sign the corporate charter, and provide the remainder of the original Taskforce with the opportunity to invest in the corporation. A provider agreement has been developed and the appropriate requirements for becoming a provider are being finalized as the recruitment for providers begins.

**Piedmont Pharmaceutical Care Network, L.L.C.**

**Mission:**

- **To encourage utilization and compensation of pharmacists for provision of cognitive services**
- **To improve the continuity of pharmaceutical care as patients transition through different health care settings**

There are many key issues that have been and will continue to be addressed by PPCN and the Taskforce. The first is to develop a group of competent, well trained pharmacist providers. Through the efforts of the Taskforce and Greensboro AHEC, the standards for the practice of clinical pharmacy in the Greensboro area have been set quite high. Even so, over 40 local pharmacists have completed an NCCPC-approved program through Greensboro AHEC and others. Beyond the need for a significant number of clinical pharmacists, the ultimate success of PPCN will rest on the quality of care provided by those pharmacists. On Sunday, April 25, an open forum was held with a group of potential providers to discuss these standards and reinforce the absolute competence of all providers in the network. Another important issue, which has been central to the entire process, will be obtaining and maintaining the acceptance of local physicians. Focus groups of local physicians have been surveyed to make certain they will buy into the concept of pharmacist providers. Many physicians have expressed interest in the concept — now the goal is to retain the "believers" and reach out further. Other critical issues/tasks are: marketing clinical pharmacy services to payors (specifically managed care organizations and large employers), advancing the role of technicians to allow pharmacists more time to provide clinical services, assisting providers in working with their employers so that they will have the time and physical space to conduct clinical services, and developing an efficient means of communicating in order to provide feedback to physicians, facilitate provider mentoring and document outcomes of services provided.

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About the Author:

*Christopher Rubino (phone: (336) 832-7244/e-mail: chris.rubino@mosescone.com) is Assistant Director, Greensboro AHEC Pharmacy Division and Clinical Assistant Professor, UNC School of Pharmacy. He served on the Greensboro IPA Charter Committee along with Michelle Bozovich, BSPharm; Brian Bray, BSPharm, Frank Burton, BSPharm; Teresa Devora, BA; Chris Dooley, BSPharm; Jean Douglas, PharmD; Pam Earnhardt, BSPharm; Larry Long, BSPharm; Peter Gal, PharmD*

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*Volume 22, Number 3* *The bimonthly publication of the North Carolina Society of Health-System Pharmacists* *May/June1999*

## *From the President*

# Opening a Door for Others

Are you willing to share your knowledge and experiences in pharmacy practice with someone interested in improving practice skills? Do you feel rewarded professionally and personally by assisting others in expanding their careers and achieving career goals? If so, NCSHP has a proposition for you. Become a member of the Mentorship Program.

*NCSHP President William Harris*

In 1998, the NCSHP Membership Committee arranged twenty mentor-mentee relationships and the feedback has been very positive. In 1999, 29 pairs have been identified. If you are unsure how you can get involved, please read on.

A **mentor** is an experienced and respected practitioner who serves as a counselor, adviser, guide and friend to a colleague, student, new graduate, technician or less experienced practitioner who aspires to grow professionally. The **mentee** must be willing to ask for help, take advice and follow through with suggestions and guidance from the mentor.

Being a mentor is similar to coaching. The mentor:

- gets to know the mentee personally
- identifies abilities and improvement areas
- encourages activities to enhance these abilities
- looks for opportunities for participation by the mentee
- sponsors entry into new or advanced practices
- guides the performance and improvement
- provides support when necessary
- shares in the successes and accomplishments.

The NCSHP Mentorship Program strives to match participants with similar practice interests and other qualities. NCSHP recommends that the mentor contact the mentee several times during the year, but the individuals set their own criteria, meeting schedules and goals. NCSHP serves to facilitate the process while the members involved enjoy the relationship and success.

*Continued on page 24*

## 1998-99 MENTORS & MENTEES

Under the leadership of then Membership Committee chair, LeAnne D. Kennedy, and Board Liaison, Julienne K. Kirk, the NCSHP Mentorship Program was successfully launched in the spring of 1998. The Mentorship Program is designed to encourage personal and professional growth through Society involvement and one-on-one interaction with a recognized NCSHP leader. The following Mentor - Mentee pairs participated in the 1998-99 Mentorship Program:

| **Mentors** | **Mentees** |
|---|---|
| **Sheila Billingsley**<br>*Wake Forest University Baptist Medical Center* | **Lori Wilson**<br>*UNC-Chapel Hill School of Pharmacy* |
| **Ken W. Burleson**<br>*Catawba Memorial Hospital* | **Wyn Sterling**<br>*Gaston Memorial Hospital* |
| **Vance Collins**<br>*Halifax Regional Medical Center* | **Amy Davis**<br>*Southeastern Regional Medical Center* |
| **Debby Cowan**<br>*Angel Medical Center* | **Lori Colemon**<br>*UNC-Chapel Hill School of Pharmacy* |
| **Steve Critz**<br>*Wilkes Regional Medical Center* | **Eugenia Key**<br>*Wilkes Regional Medical Center* |
| **Dan Garrett**<br>*North Carolina Association of Pharmacists* | **Sandeep Singh**<br>*UNC-Chapel Hill School of Pharmacy* |
| **Anna Garrett**<br>*Consultant Pharmacist* | **Caroline Johnson**<br>*Advanced Homecare* |

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# *Dilemmas*

## ALTERNATIVE MEDICINE: The Discussion Continues...

by Mary E. Herring, Pharm.D.
Pharmacy Practice Resident, Moses Cone Health System

Alternative medicine therapies continue to be debated in most medical professional circles due to limited scientific data. As the number of persons using "dietary supplements" increases pharmacists are asked daily for recommendations of these products in a number of ailments, such as arthritis, depression, and sleep. As the most trusted profession, our patients expect us to provide the most accurate and appropriate product information.

How do we find the needed information to provide appropriate care? New texts are available today, such as the Commission E monographs.[1] The monographs provide over 380 entries of herbal compounds including those with documented benefit in primary German literature. But a recent editorial response by Drs. Angell and Kassirer in the *New England Journal of Medicine* cautions use of this text as a reference for medical practice due to a lack of primary literature citations.[2]

How do we ensure that the agents we recommend to patients are safe and efficacious? This question is more difficult as these agents are not currently regulated by the US Food and Drug Administration as drugs. These products may be sold without FDA approval under The Dietary Supplement Health and Education Act. Without FDA regulations to stipulate good manufacturing practices, pharmacists must rely upon the good faith of manufacturers to provide unadulterated or misbranded products for their patients. Problems currently associated with this lack of regulation include variations in quantification of active ingredients and recommendations for conversion from one branded product to another manufacturer's product.

Primary literature does not yet include complete documentation of potential drug interactions between herbal products and commonly used pharmacologic agents. This is of particular concern when patients are maintained on narrow therapeutic index agents or those with additive adverse event profiles.

What actions have been taken to protect patients in one health system? The Moses Cone Health System Pharmacy Committee voted in January 1998 to not dispense any herbal products for inpatients. Additionally, no repackaging of agents as patient's home medications for in-house use is allowed. This decision was based on lack of information of drug-supplement interactions and lack of standardization among companies' manufacturing practices. The Committee questioned the appropriateness of the agents in the setting of acute illness. As this decision was made, the Committee reaffirmed its' previous policy of providing only drugs approved by the Food and Drug Administration or under investigational protocol for use in the Health System.

When scientific and clinical information becomes available, this decision will require reconsideration. Until then, the pharmacist should evaluate each product carefully for patients when asked, stating what is known and unknown. When patient care problems are noted, every pharmacist should submit this information to the FDA's MedWatch Program. This information may be necessary before the FDA will readdress its current classification system for these agents. ◆

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# GAP_TAB: Filling the GAP With Qualified Technicians

**by Faye Elliot, CPhT** and **Alexis Kiger, R.Ph.** with Teresa Devora, B.A.

There is a new group in Greensboro working hard for technicians. They are the Greensboro Area Pharmacy Technician Advisory Board (GAP_TAB) a working board of the Greensboro Area Health Education Center Pharmacy Education Services. GAP_TAB helps facilitate the educational and career processes for technicians in the Greensboro AHEC eight-county region. In addition, they are reaching out to the rest of North Carolina to create a positive career image for pharmacy technicians. Their mission statement best summarizes their goals: *To promote career paths for pharmacy technicians through recruitment, education, certification and retention thus providing efficient and accurate patient care in advancing pharmacy practice.*

Currently, a person with very little experience in pharmacy can get a job as a pharmacy technician. In fact, some technicians who have been working in their positions do not possess the basic skills to properly assist pharmacists. The turn-over rate for technicians is unbearable to many pharmacists due to the training needs of new personnel. But even with the difficulties in properly hiring and training technicians, imagine life without pharmacy technicians! GAP_TAB whose slogan is "filling the GAP with qualified technicians" has partnered with several organizations to fulfill its mission.

One such organization is the Piedmont Pharmaceutical Care Network, LLC, an independent provider association (IPA) of pharmacists who are redefining the role for pharmacy in health care. This IPA format is a starting point for a state-wide initiative to create a network of pharmacists to provide, promote and arrange clinical pharmacy services in all practice settings. Pharmacists are highly trained individuals with the ability to provide vital information to a health care team and the patient to optimize drug therapy. However, pharmacists must have properly trained, career-minded technicians to help them fulfill their distribution duties as they step out from behind their counters to implement clinical services. This is where GAP_TAB steps up to take the challenge in affiliation with:

- UNC School of Pharmacy
- North Carolina Board of Pharmacy
- North Carolina Area Health Education Centers (NC AHEC)
- Moses Cone Health System (MCHS)
- North Carolina Association of Pharmacists (NCAP)
- North Carolina Center for Pharmaceutical Care (NCCPC)
- Piedmont Pharmaceutical Care Network (PPNC)

Already, GAP_TAB is beginning to create several avenues to educate pharmacy technicians in the retail setting. In cooperation with Greensboro AHEC Pharmacy Education Services, the first North Carolina 10-week technician preparatory course for the PTCB examination is coming to a close with 18 currently practicing technicians (one-third are retail chain technicians) who were ready to sit for the March 13 national certification examination. Additionally, GAP_TAB, in cooperation with NCAP, is planning a continuing education session this summer specifically geared to retail chain pharmacy technicians supported by NCAP.

An exciting project, spearheaded by Greensboro AHEC Health Careers/ Minority Workforce Development, is a partnership between Dudley High School, GAP_TAB and CVS Pharmacy. This effort involves setting up a two-semester pharmacy technician curriculum to train high school students to become retail pharmacy technicians. The students will be required to do an externship with participating retail pharmacies in order to pass the course. The intent of the program is to provide retail pharmacists with a career-minded, well-trained pool of pharmacy technicians to recruit and retain.

Another activity GAP_TAB has completed is sending a letter via NCAP Executive Director Dan Garrett to district managers (or equivalents) of retail chain pharmacies in the state to help promote our efforts with retail pharmacy technicians and recruit delegates for the advisory board. GAP_TAB also sent representatives to "Pharmacy Day in the Legislature" to help determine avenues for legislative changes regarding technicians. Board members have already begun efforts to effect legislative issues at the state level.

Pharmacy technicians in any practice setting are invited to represent their concerns and interests with membership to GAP_TAB. For meeting dates and locations, please call 336.832.7570 or email the authors.

## About the Authors:

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***Continued from page 21***

You do not have to be a Pharmacy Director or noted Professor to qualify to be a mentor. Think of the mentor as a friend who can see over the horizon, who opens doors that the mentee may not know how to discover or open alone, and who enables the mentee to develop into a better practitioner or future leader. The qualities most often identified in mentors include:

- caring and understanding
- personable and open
- willing to listen and share ideas
- willing to teach others.

NCSHP is honoring the twenty mentors who volunteered for this program in 1998 (See the list 98-99 Mentors & Mentees on page 19) We need more members to participate in this rewarding program. If you are willing, please contact Beth Williams, Regina Schomberg, Julie Kirk, or other members of the Membership Committee for more information. Your years of experience and professional insights are invaluable to young practitioners who are seeking support, guidance and opportunity to enhance their practice skills.

NCSHP is committed to fostering personal and professional growth of our future leaders. The Mentorship Program offers this invaluable experience.◎

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*Senior PHARMAssist, continued from page 8*

Medicaid eligibility level but have incomes less than 150% of the federal poverty level. There are two different categories of clients: funded and unfunded. "Unfunded" clients are those individuals who do not meet the inclusion criteria. Senior PHARM*Assist* supplies them with information about the prescription assistance programs from the drug manufacturers (which can be paper intensive and often short-lived) and about local agencies that provide short-term funding. There is no charge for this service. An "unfunded" older adult is also eligible for a medication review, but the sliding scale fee is based on their ability to pay.

The goal with Senior PHARM*Assist's* "funded" clients is to help older adults who have very limited financial means remain as healthy, active, and independent as possible. The program accomplishes this by helping eligible seniors pay for their medications; conducting detailed, prospective medication reviews every six months; and encouraging clients to take active roles in their own healthcare. Many of our clients are struggling to stay in their homes. They have multiple chronic conditions, including: 22% who have cancer; 23% who have had a stroke; 28% who have had asthma, bronchitis or emphysema; 33% who have had diabetes; 56% who have had heart disease; and 74% who have had hypertension.

The "funded" program works with community pharmacies and links these pharmacies via the Pharmacy Network National Corporation computer system. Clients are given a plastic card (third-party insurance card) to identify themselves as participants. This system allows seniors with low incomes to avoid the stigma of obtaining "free" medications from a "poor" person's pharmacy. The computer linkage allows community pharmacists to screen for drug interactions even when medications are dispensed at different stores. A computer at the central office allows for immediate enrollment and updating after clients are seen. Clients pay the first eight dollars for up to a 100-day supply of each prescription, which provides revenue and strengthens the clients' ownership in the program and Senior PHARM*Assist* pays the rest. All local pharmacies are contributing by accepting a reimbursement rate $2 less than the Medicaid rate. The program only helps pay for medications on their geriatric formulary. Formulary decisions are based on direct cost, effectiveness, and safety in the geriatric population, thus encouraging appropriate prescribing as well as controlling costs.

### The Medication Review

Clients are seen at six-month intervals to be re-certified and to thoroughly evaluate their medication use. The medication reviews begin with a brief medical history, then a pharmacist goes over each of their medications one by one. Clients report how they take each medication and why. For things like insulin, inhalers, and eye drops, clients show the pharmacist how they are using them, and, if necessary, the pharmacist demonstrates proper technique. The pharmacists notes whether clients can read their labels and open their bottles. Staff has identified clients who were experiencing pseudoparkinsonism, depression, and confusion from their medications. Medication reviews have uncovered clients who had histories of stroke or atrial fibrillation but who weren't on antithrombotic therapy, and the pharmacists have identified clients who were taking two ACE-inhibitors at the same time and others who were very likely dig toxic. The list goes on and continues to grow.

### Interventions

To enhance medication adherence and help prevent medication mishaps, the pharmacists at Senior PHARM*Assist* perform several interventions. They give clients pill boxes, spacers, peak flow meters, insulin syringe magnifiers (all of which have been donated) and make medication calendars when appropriate. They monitor blood pressures and blood glucoses. They educate women on calcium for their bones. They inform clients on the potential benefits of taking an aspirin a day, getting the immunizations they need, and preventing versus treating constipation. Kegel exercises are reviewed with women experiencing urinary incontinence.

The staff contacts family members, caregivers, social workers, home health providers, pharmacists and physicians when indicated. Senior PHARM*Assist* staff lets them know what problems or potential problems they have identified, the steps taken to alleviate the problems, and suggestions on ways they may help clear up current problems or prevent future ones. But probably the most important thing Senior PHARM*Assist* does is LISTEN. By listening and encouraging clients to talk, staff often discovers that most of their reasons for noncompliance are intentional—that clients have side effects or *perceive* side effects to one or more medicines—or just fear taking so much medicine in general. Sometimes they are on the wrong track, and Senior PHARM*Assist* tries to clear up their misconceptions and put them at ease. But very often they are voicing valid concerns.[7]

### Medication Record

Possibly our most important intervention is the creation of a medication record for each client. These records list all of their medications (legend and OTC), as well as medication allergies and adverse effects. Clients are responsible for showing these records to all of their healthcare providers, hence providing each provider with a complete medication profile and preventing possible medication mishaps.

### The Mission of Senior PHARM*Assist:*

- Educates Durham County senior citizens about preventive health measures
- Consults with seniors and healthcare providers about safe and effective medication use, and
- Provides financial assistance for necessary medications to seniors with low incomes.

*Continued on next page*

### Evaluation

Program evaluation is crucial for Senior PHARM*Assist*. Client data are collected on an ongoing basis at six-month intervals. The primary focus of the client evaluation is to assess medication adherence, health services utilization, functional assessment, and satisfaction. The preliminary data demonstrate that after clients have been in the program one year, they have 31% fewer emergency room visits and 29% fewer inpatient hospital stays. The primary focus of the volunteer, healthcare and social service provider evaluations are to assess their satisfaction with our services, which is vital for program sustainability.

### Funding

So far, Senior PHARM*Assist* has been supported primarily by charitable foundations. Because foundations generally provide funding for startup projects versus ongoing services, the program is now working diligently to increase revenue from the Durham community via individual and corporate contributions. Several of the twelve statewide pharmaceutical assistance programs across the country receive funding from special sources (for example, lottery, casino, or tobacco tax revenues), but most are supported by general state revenues.

### Conclusion

The combination of medication access and pharmaceutical care for older adults with limited incomes is a winning proposition for many stakeholders. Pharmacists can use their counseling skills; prescribers can appreciate teamwork to optimize drug therapy; clients lead healthier lives; and ultimately, taxpayers shift their funds from expensive health interventions (e.g. unnecessary hospitalizations and nursing home placements) to preventive pharmaceutical care. Though North Carolina currently lacks a statewide program, the General Assembly should consider the need for outcomes-based pharmaceutical care including financial assistance for those older adults who struggle to remain independent in the community.

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## *Ward Drug Company, Continued from page 11*

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2. Relying on insurance companies for reimbursement for any type of product or service is a false sense of reality.
3. If a patient places value in your services, they will reimburse you out of their own pocket.

### What were your stumbling blocks?

1. Changing my own mindset and the mindset of my employees.
2. The lack of empowerment of my employees.

### Where are you heading now with your practice?

Beginning July 1999, Ward Drug Company will be initiating a "Feet Can Last a Lifetime" Foot Care Program in attempt to decrease the number of diabetic foot infections, decrease the amputation incidence, and improve the overall quality of health of persons with diabetes. Our Care Plan will include a choice of bimonthly or periodic foot examinations, training of how to properly use a microfilament to measure neuropathy, professional advice to help patients take better care of their feet, a free measurement for diabetic shoes, a private foot exam and continuity of care with personal records, a 10-minute instruction video on caring for your feet, written material, and a sample basket of products recommended for use on diabetic feet. Our purpose for initiating this program is to assist patients in recognizing abnormalities of the foot in order that they may seek early care from their physician, and to help patients prevent complications.

Dr. Laura Brewer is moving into a collaborative practice one day per week with four physicians and four physician assistants beginning in May with expectations of that increasing to three days per week. Her duties will include coordinating a lipid clinic and handling pharmacotherapy issues as they arise.

We just finished hosting a Women's Health Symposium on natural hormone replacement therapy. Two hundred women in the Eastern Carolina area attended. We are now focusing compounding initiatives on increasing patient awareness of natural hormone replacement therapy.

We are also concentrating on diversifying our veterinary compounding.

Our Diabetic Shoppe continues to grow at an exponential rate, and we are searching for ways to expand that practice with more diversity.

## *COX-2 inhibitors, Continued from page 17*

Not surprisingly, there are many COX-2 inhibitors at various stages of research and development. However, manufacturers are eager to keep public details of their research ventures to a minimum as this new class of NSAIDs is expected to generate substantial revenue in the future. At least two new COX-2 inhibitors have been formally named. Merck plans to launch their COX-2 inhibitor rofecoxib (Vioxx®) in early summer and meloxicam (Mobic®), comarketed by Abbott Laboratories and Boehringer Ingleheim is currently under FDA review.

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# COX 2 INHIBITORS: AN INTRODUCTION

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*Gossel*

*Wuest*

**Goals.** The goal of this lesson is to discuss the role of nonsteroidal anti-inflammatory drug (NSAID) therapy with focus on the potential benefits of selective inhibition of the enzyme cyclooxygenase-2 (COX-2).

**Objectives.** At the conclusion of this lesson, successful participants should be able to:

1. differentiate between the normal physiologic functions of the enzymes COX-1 and COX-2;
2. recognize the pharmacologic agents that are reported to have a preferential inhibitory action on COX-2;
3. identify pharmacologic principles of NSAID toxicity which have led to development of selective inhibitors of COX-2; and,
4. identify the most common adverse effects of NSAIDs and how they are produced.

Nonsteroidal anti-inflammatory drugs (NSAIDs) have improved the quality of life for millions of sufferers from arthritis and other painful conditions. It is estimated that approximately 1 percent of the U.S. population takes an NSAID for the treatment of osteoarthritis, rheumatoid arthritis, premenstrual tension, and a variety of musculo-skeletal disorders that involve pain, stiffness and other symptoms.

NSAID therapy is not without risks, however, especially gastrointestinal and renal toxicity. The extent of adverse events with NSAIDs is staggering, reported to occur more often than with any other class of drugs. Medical costs associated with hospitalization from gastrointestinal complications exceed $380 million annually. Total costs are reported at almost $4 billion each year in the U.S.

This lesson elaborates on the usefulness of NSAIDs in the treatment of pain. It discusses the pharmacologic rationale for development of adverse effects that are reported in the gastrointestinal tract. It then presents the reason for development of NSAIDs which inhibit one specific isoform of the enzyme cyclooxygenase in an attempt to enhance the safety profile.

### NSAIDs — The Drugs

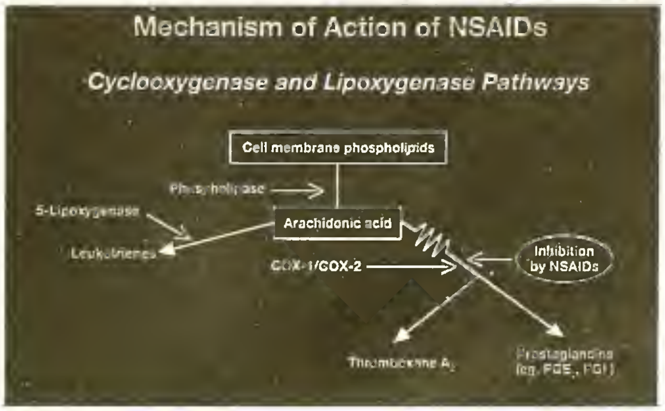
NSAIDs can be classed into groups in a variety of ways, as can be noted in standard pharmacology texts. The drugs have different pharmacokinetic profiles, and dosing schedules should be based on their plasma half-lives. Agents with a long half-life, for example, are dosed once or twice a day. These drugs may improve compliance in forgetful patients.

### Mechanism of Action

All NSAIDs inhibit prostaglandin synthesis as their primary mechanism of action (Figure 1). A normal component of membrane phospholipids, arachidonic acid, is converted into prostaglandins and thromboxane $A_2$ by the enzyme cyclooxygenase (COX).

Synthesis of prostaglandins is tissue specific. The most prevalent prostaglandins in the gastroduo-denal mucosa are prostaglandin $E_2$ ($PGE_2$) and prostaglandin $I_2$ ($PGI_2$; prostacyclin). Arachidonic acid can also be converted

**Figure 1.**



Mechanism of Action of NSAIDs

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into a variety of lipoxygenase-derived products (leukotrienes) which play an important role in the inflammatory process.

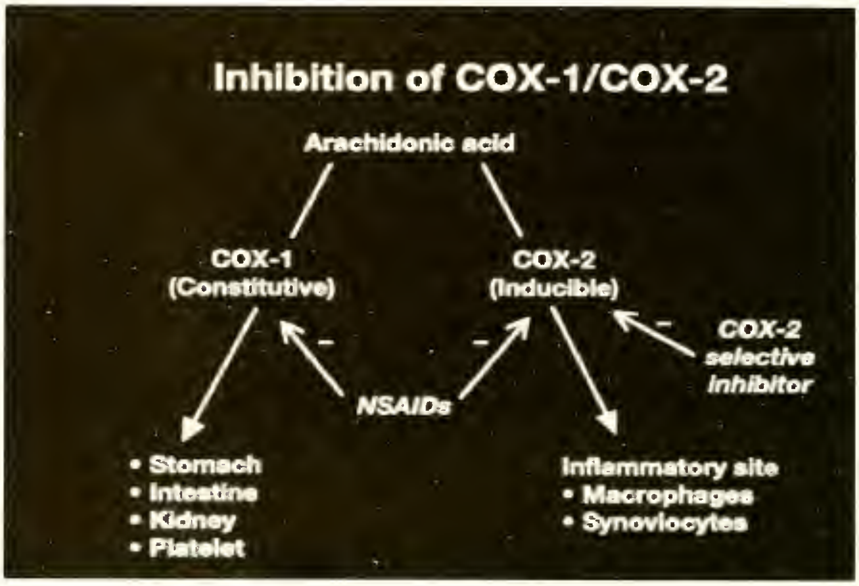
Cyclooxygenase. Cyclooxy-genase (COX) exists in two isoforms, COX-1 and COX-2.

It is proposed that COX-1 and COX-2 serve different physiologic functions. COX-1 is expressed constitutively. This means it is synthesized continuously. The function of COX-1 is to stimulate synthesis of prostaglandins that regulate normal cell activity, most notably platelet aggregation, homeostatic function of the vasculature, the gastrointestinal mucosa, and the renal system. In contrast, the action of COX-2 is more limited. COX-2, like COX-1, is constitutively expressed, but at low levels. However, its production is induced dramatically during the inflammatory process (Figure 2). A single amino acid variation at position 509 of cyclooxygenase (i.e., valine, COX-1; isoleucine, COX-2) differentiates the two forms.

Data from numerous studies strongly suggest that the anti-inflammatory action of NSAIDs results primarily from inhibition of COX-2. Many of the adverse effects (e.g., gastrointestinal toxicity and inhibition of platelet function) reported for these drugs are believed to be due to inhibition of COX-1. Until recently when the first nonsteroidal anti-inflammatory drug (i.e., celecoxib; Celebrex/Searle) which inhibited COX-2 preferentially was approved by FDA, all of the currently available NSAIDs inhibited both COX-1 and COX-2 to varying degrees.

With discovery of COX-2 and hypothesis that its selective inhibition would provide the potent anti-inflammatory and analgesic activity of NSAIDs without influencing COX-1 and its normal physiologic functions, research in this area has been intensive. The goal was to develop compounds that possessed a high degree of selectivity for the inducible form (COX-2) while sparing the constitutive form (COX-1). The approval of celecoxib brings the first member of this group to the market.

**Figure 2.**



## Adverse Effects of NSAIDs

The American College of Rheumatology suggests the following guidelines for monitoring the effects of medications used in the treatment of rheumatoid arthritis. A *rare* adverse effect is one that occurs in less than 1 percent of patients using the agent. An *uncommon* adverse effect occurs in 1 to 10 percent of patients. A *common* adverse effect occurs in more than 10 percent of patients.

Adverse effects attributed to NSAIDs that are rare include confusion, depression, rash, headache, renal insufficiency, and serious hepatic toxicity. NSAIDs may also inhibit platelet aggregation reversibly and prolong bleeding time. Patients with prior aspirin hypersensitivity are at risk for developing bronchospasm when taking NSAIDs.

**Gastrointestinal Complications.** The primary adverse effects associated with NSAID therapy result from their action to alter gastric and duodenal mucosal defense mechanisms. This outcome is mediated primarily via inhibition of synthesis of mucosal prostaglandins. The action is both local and systemic, with systemic effects much more prominent.

It has been reported that up to 46 percent of patients receiving NSAIDs experience some type of gastrointestinal adverse effect, the most common being dyspepsia. This classifies certain gastrointestinal complications as *common* adverse events. Of greater concern is the prevalence of peptic ulcers in patients receiving NSAID therapy. Most studies report an incidence ranging from 10 to 30 percent of users. This represents a 10- to 30-fold increase in incidence over that in the general population.

Symptomatic ulcers and their complications such as upper gastrointestinal bleeding, perforation, and gastric outlet obstruction which are potentially life-threatening are reported in 2 percent to 4 percent of patients who take NSAIDs for a year. These complications frequently occur without warning symptoms and have been reported within days of initiation of therapy with NSAIDs. Acute drug use, therefore, is not free of risk.

Presence or absence of symptoms is not a reliable predictor of gastrointestinal adverse effects in patients taking NSAIDs. One study evaluated patients requiring surgical intervention for gastric hemorrhage and/or perforation, or who died of peptic ulcer disease. Study results noted that 58 percent of patients with NSAID-induced complications were asymptomatic prior to surgery, compared with 25 percent of patients who were not taking NSAIDs and were asymptomatic.

The Arthritis, Rheumatism and Aging Medical Information System (ARAMIS) is a databank of arthritis patients in the U.S. and Canada. An analysis of nearly 2,000 rheumatoid arthritis patients enrolled in it revealed that 81 percent of those hospitalized with serious gastrointestinal complications were symptom-free. Gastrointestinal hospitalizations occurred, on average, approximately 17.3 months after patients started to take NSAIDs. The reason so many patients were asymptomatic has been attributed to the analgesic activity of NSAIDs which masked the warning signs of GI tract adverse reactions

From the ARAMIS study, it can be extrapolated that of the two million sufferers of rheumatoid arthritis in the U.S., approximately 26,000 will be hospitalized each year for NSAID-associated gastrointestinal adverse effects. It can also be calculated that approximately 76,000 persons out of an estimated 13 million users of NSAIDs in the U.S., will be hospitalized each year for NSAID-induced gastrointestinal adverse events.

The death rate among patients in the ARAMIS study from complications of NSAID gastrointestinal adverse events was 0.19 percent. This contrasted to an expected annual death rate from these events of 0.08 percent. Thus, it can be estimated that approximately one in every 1,000 patients with rheumatoid arthritis in the U.S. will die from NSAID-induced gastrointestinal complications each year. Using this calculation, approximately 7,600 persons in the U.S. will die each year from NSAID-induced gastrointestinal events.

The risk of death resulting from gastrointestinal complications from NSAID use may be compared with risk from other common causes. Death associated with gastrointestinal events in patients with rheumatoid arthritis taking prescription doses of NSAIDs has been reported to be approximately 0.2 percent per year. This figure corresponds with the risk of death from cigarette smoking or from cancer. It is 10 times greater than the risk of death resulting from a motor vehicle accident or home accident.

### Gastric Protective Mechanisms

The stomach lumen is acidic with a normal pH of 1-2. The normal gastric mucosa is protected against this hostile environment of acid and pepsin by a number of defense and repair processes.

A layer of mucus rich in bicarbonate is secreted from surface epithelial cells. This increases the pH at the mucosal surface, despite the low luminal pH of 1-2.

The surface of epithelial cells exposed to the stomach lumen can resist back diffusion of acid directly. Moreover, epithelial cells repair defects in the mucosal layer rapidly through a process called *restitution*. This occurs because existing epithelial cells migrate along the basement membrane to fill in defects created by the sloughing of cells.

Blood flow into the mucosa delivers bicarbonate, oxygen, and nutrients to cells, and provides for disposal of back-diffused acid. Evidence is strong that decreased mucosal blood flow significantly impairs mucosal resistance to injury.

Endogenous prostaglandins have an active role in helping defend the gastric mucosa against damage. Prostaglandins inhibit acid secretion, stimulate mucus and bicarbonate secretion, increase mucosal blood flow, and enhance mucosal regeneration. This forms the therapeutic basis for combining the prostaglandin analog, misoprostol, with the NSAID diclofenac sodium, marketed as Arthrotec.

Inhibiting prostaglandin synthesis decreases the anti-secretory effects on gastric acid production, reduces bicarbonate synthesis, impairs gastric mucosal blood flow and, overall, impairs the adaptive cytoprotective mechanism. Because they inhibit platelet aggregation, NSAIDs can enhance upper gastrointestinal bleeding. The local effects of NSAIDs combined with their systemic actions on prostaglandin synthesis and platelet aggregation set the stage for development of ulcers and ulcer complications.

### Risk Factors for Gastrointestinal Toxicity.

Age is the primary risk factor for NSAID-related gastrointestinal complications in patients with rheumatoid arthritis. Other risk factors for gastrointestinal toxicity in patients taking NSAIDs are listed in Table 1. An evaluation of nearly 2,000 patients with rheumatoid arthritis from the ARAMIS study reported that persons who recently used H2-receptor antagonists and antacids, but did not experience an NSAID-related adverse effect, were at increased risk of NSAID-induced gastrointestinal complications.

### Therapeutic Outcomes of NSAIDs

The pharmacologic actions of the various NSAIDs upon the pain response are essentially identical when measured objectively. However, analgesic responses to full therapeutic doses are often subjective due to considerable inter-patient variability in response (i.e., extent of symptom control) to each drug. When one considers the average therapeutic benefit of all NSAIDs in all patients, a clinically significant difference between drugs is difficult to define. However, specific patient populations may experience enhanced analgesic relief from one particular NSAID over another.

The same reasoning is not valid when assessing drug action on the inflammatory response. The extent of inflammation and/or its inhibition can be measured objectively. Since analgesia normally corresponds with degree of reduction of inflammation, it can be extrapolated that reduced inflammation equates to increased analgesia.

When a particular NSAID fails to work or the patient becomes tolerant to it, it is appropriate to try a drug from an alternate chemical class. The same is true when a given NSAID exerts excessive adverse effects or toxicity in a patient.

Several studies have reported marked differences in clinical response to NSAIDs among different patient groups. Variations in their physicochemical properties, pharmacology, pharmacokinetics, and pharmacodynamics may partly explain the differences in clinical response. Variability in patient response to NSAIDs, the large size of the target patient population, and the extent and nature of adverse effects associated with traditional NSAIDs have stimulated development of newer therapeutic agents and new delivery systems.

### Selection of an NSAID

Selection of an appropriate NSAID must consider a variety of patient factors. Some, such as risk factors, compliance, tolerability, and patient preferences, are interrelated. Most patients with rheumatoid arthritis require NSAIDs to reduce joint pain and swelling and improve function. Whether or not to use NSAIDs at full therapeutic doses in patients with osteoarthritis depends on their response to non-opioid analgesia combined with nonpharmacologic measures.

The American College of Rheumatology has stated that elderly patients, patients with comorbid diseases, and persons taking concurrent medications that reduce renal blood flow must be monitored carefully for renal insufficiency when taking NSAIDs.

The dosing regimen is also a consideration in drug selection. Frequency of dosing affects compliance. Since NSAIDs are commonly taken by the elderly who often have comorbid conditions, there is a potential for interaction between NSAIDs and other drugs.

Nonacetylated salicylates (e.g., salsalate) and ibuprofen have been reported to have a diminished risk for toxicity. It is possible that this is dose-related rather than therapeutic advantage.

Modifications in formulation, different routes of administration, and development of prodrugs have been attempted to reduce the incidence of upper GI bleeding. Controlled pre- and post-marketing studies have failed, to date, to support consistent reduced toxicity resulting from these modifications.

The risk also remains the same for enteric-coated aspirin and buffered aspirin compared with plain aspirin. Enteric-coated preparations of non-aspirin NSAIDs, and NSAIDs that are administered as suppositories or intravenously also continue to be associated with gastric and duodenal ulceration. This is because NSAID-induced gastric ulceration occurs from within the gastric epithelial cells via prostaglandin inhibition, rather than as a result of direct action on these cells while the drug remains in the stomach lumen.

### Celecoxib

The first cyclooxygenase-2 (COX-2) inhibitor approved for use in the U.S., celecoxib (Celebrex/Searle), is indicated for relief of signs and symptoms of osteoarthritis and rheumatoid arthritis in adults. Clinical trials are underway to evaluate its use in acute and chronic pain in addition to its osteoarthritis and rheumatoid arthritis indications. Pfizer will co-market the drug product with Searle.

Celecoxib is reported to be approximately 375 times more selective for COX-2 than COX-1. It is approved for use in osteoarthritis at a dose of 200mg once daily or 100mg twice daily. Doses of 100mg or 200mg twice daily are recommended for rheumatoid arthritis. Celebrex is not approved for use in patients under 18 years of age.

Celecoxib labeling states, "In all three studies that included naproxen 500mg b.i.d., and in the study that included ibuprofen 300mg t.i.d., Celebrex was associated with a statistically significantly lower incidence of endoscopic ulcers over the study period."

Two other COX-2 inhibitor drugs may follow Celebrex shortly: rofecoxib (Vioxx/Merck) and meloxicam (Mobic/Boehringer Ingelheim). Like celecoxib, both are administered in once-daily doses.◉

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# Continuing Education Quiz

1. Cyclooxygenase is the enzyme involved in the conversion of:
   a. arachidonic acid into prostaglandins.
   b. leukotriene I into leukotriene II.
   c. prostaglandins into arachidonic acid.
   d. leukotriene II into leukotriene I.

2. The most predominant prostaglandins in the gastroduodenal mucosa are:
   a. $PGA_1$ and $PGD_1$.
   b. $PGC_1$ and $PGB_2$.
   c. $PGE_2$ and $PGI_2$.
   d. $PGG_2$ and $PGH_1$.

3. The type of cyclooxygenase that is synthesized continuously, rather than being induced dramatically during the inflammatory process is:
   a. COX-1.
   b. COX-2.
   c. COX-3.
   d. COX-4.

4. Studies strongly suggest that the anti-inflammatory action of NSAIDs results primarily from inhibition of:
   a. COX-1.
   b. COX-2.
   c. COX-3.
   d. COX-4.

5. Many of the adverse effects caused by NSAID-induced GI tract toxicity and inhibition of platelet function are believed to be due to inhibition of:
   a. COX-1.
   b. COX-2.
   c. COX-3.
   d. COX-4.

6. The primary adverse effects associated with NSAID therapy result from their ability to:
   a. inhibit cytochrome P-450 enzyme systems.
   b. stimulate the chemoreceptor trigger zone.
   c. inhibit platelet aggregation and prolong bleeding time.
   d. alter gastric and duodenal mucosal defense mechanisms.

7. The process by which the gastric epithelial tissue repairs defects created by the sloughing of cells is called:
   a. remodeling.
   b. reconstruction.
   c. re-epithelization.
   d. restitution.

8. Endogenous prostaglandins have an active role in helping to defend the gastric mucosa against damage by all of the following mechanisms EXCEPT:
   a. inhibition of acid secretion.
   b. increased mucosal blood flow.
   c. inhibition of bicarbonate secretion.
   d. stimulation of mucus secretion.

9. NSAID-induced development of ulcers and ulcer complications result from:
   a. local inhibition of prostaglandin synthesis only.
   b. systemic inhibition of prostaglandin synthesis only.
   c. both local and systemic inhibition of prostaglandin synthesis.
   d. neither local nor systemic inhibition of prostaglandin synthesis.

10. The first COX-2 inhibitor approved for marketing in the U.S. is:
    a. Arthrotec.
    b. Celebrex.
    c. Daypro.
    d. Relafen.

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# Letters to the Editor

# PHARMACY MAKES INROADS AT THE STATE LEVEL

## Pharmacy Represented on the NC Health Choice for Children Task Force...

On April 21, 1999, I was excited to attend my first meeting as the pharmacy representative on the NC Health Choice for Children Task Force committee. For those not familiar with the NC Health Choice for Children, it is a state and federally funded program that brings health insurance coverage to children who belong to families ineligible for Medicaid, but cannot afford private insurance.

One of the major goals of the task force this year is to enroll 70,000 uninsured children. Since the program's inception in October 1998, more than 32,000 children have been enrolled to receive comprehensive health coverage for one year. Services range from pharmaceutical, medical, dental, special hearing and vision, and all claims are filed with Blue Cross/Blue Shield of NC.

Pharmacy's involvement with NC Health Choice for Children is two-fold. First, we will dispense medications to these children at a rate of AWP-10% plus a $6 dispensing fee. Families that earn a yearly income more than 150% of the federal poverty level will have a $6 co-pay. Those that make less than 150% of the poverty level are not subject to a co-payment.

The second level of pharmacy involvement will come with disease management and pharmaceutical care. This year the task force will target asthma management for these children which provides a wonderful opportunity for trained pharmacists in asthma management. Reimbursement issues have not been addressed as the task force was just notified of pharmacy's potential benefit in providing optimum health care to these children. I anticipate further progress in these areas by the next task force meeting in May and will keep the North Carolina Association of Pharmacists (NCAP) informed.

This is a good opportunity for pharmacy to help the children and to help inform the medical community and state government of pharmacy's potential to provide optimum health care. If anyone has an interest in this area and would like more information, please contact Matthew P. Mielke at the addresses listed below, or Dan Garrett at NCAP.

Matthew P. Mielke, Pharm.D., R.Ph.
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## ... and on the North Carolina Health Information and Communication Alliance

NCHICA is the North Carolina Health Information and Communication Alliance. It was started with the support of the governor to support and improve the flow of health care information within the state of North Carolina. NCHICA membership includes organized health professionals, health information professionals, communication companies, companies who provide health-related products, payors and health institutions. Its members represent all parts of the health care delivery system, including managed care, long-term care, public health, hospitals, home care and clinics.

NCHICA extended an invitation to NCPhA last year. We have joined and have a seat on the "Standing Advisory Committee." The Standing Advisory Committee is made up of representatives from the practice of health care. Its membership consists of a physician, nurse, pharmacist, medical records director, long-term care administrator, public health worker, home care nurse and hospital administrator. The goal that the Standing Advisory Committee has set is to have a "Paperless Health Record by the Year 2010." This goal is envisioned as a way to facilitate communication between health care professionals and improve the health and well being of the citizens of North Carolina. This, of course, is an ambitious goal. NCHICA has begun the first steps in achieving this goal by conducting focus groups in which health care professionals can discuss with communication and information system professionals the challenges we face in achieving this goal. NCHICA has also been involved with legislation to promote the protection of patient confidentiality and privacy while supporting improved communication between health care providers. As your representative to NCHICA I will be meeting with many of you to discuss how pharmacy can support this iniative and to review the barriers and opportunities our profession can gain from improved communication. I look forward to sharing with you.

Leslie Mackowiak, R.Ph., MS
Macko001@mc.duke.edu

The Carolina Journal of Pharmacy welcomes letters from NCAP members and others. Letters should be limited to 250 words and may be edited for clarity or length. Please address all letters and other correspondence to:

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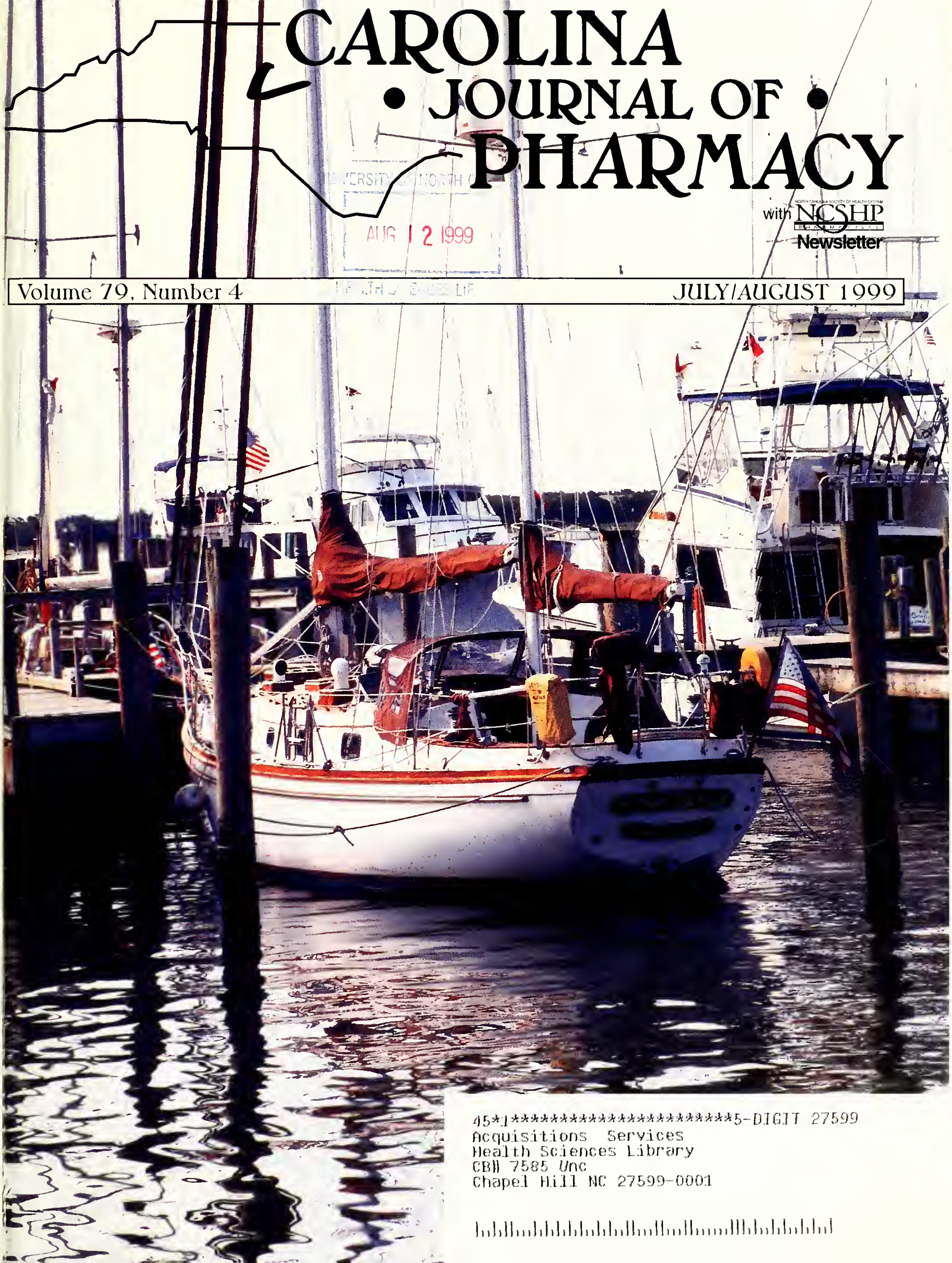

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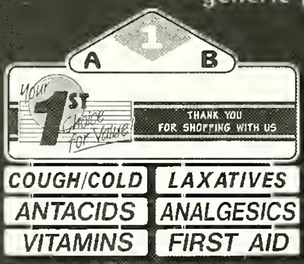

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*A plaintive sailboat bobs in the water at Atlantic Beach, NC, site of the 1999 Convention. Photo courtesy of Kevin Almond.*

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Daniel G. Garrett
Executive Director

> ***"Whatever you shall accomplish in the work of the Pharmaceutical Association of North Carolina, to exalt the standing and preserve the order and dignity of your profession, will not only confer honor upon yourselves, but will redound to the comfort and security, and indeed, bring daily blessings to the whole people."***
>
> **Taken from the comments of Dr. Eugene Grissom, addressing NCPhA's founding convention in 1880.**

# PHARMACEUTICAL CARE FOR THE 21ST CENTURY

Thanks to five years of collective effort from pharmacists across the state, we can now celebrate passage of the Clinical Pharmacist Practitioner Act. The Act publicly recognizes that pharmacists do more than simply fill prescriptions. The notion of clinical pharmacy — in which the focus of the pharmacist's knowledge is on the patient rather than the pill — has been around since the 1960s. The governor signed the bill into law on July 14, formalizing the Legislature and the North Carolina Medical Society's recognition of pharmacists' valuable clinical contributions to patient care.

For years pharmacists have been clamoring for the Board of Pharmacy, the Schools of Pharmacy and the Legislature to move pharmacists from a product focus to a knowledge-based profession, but nothing changed.

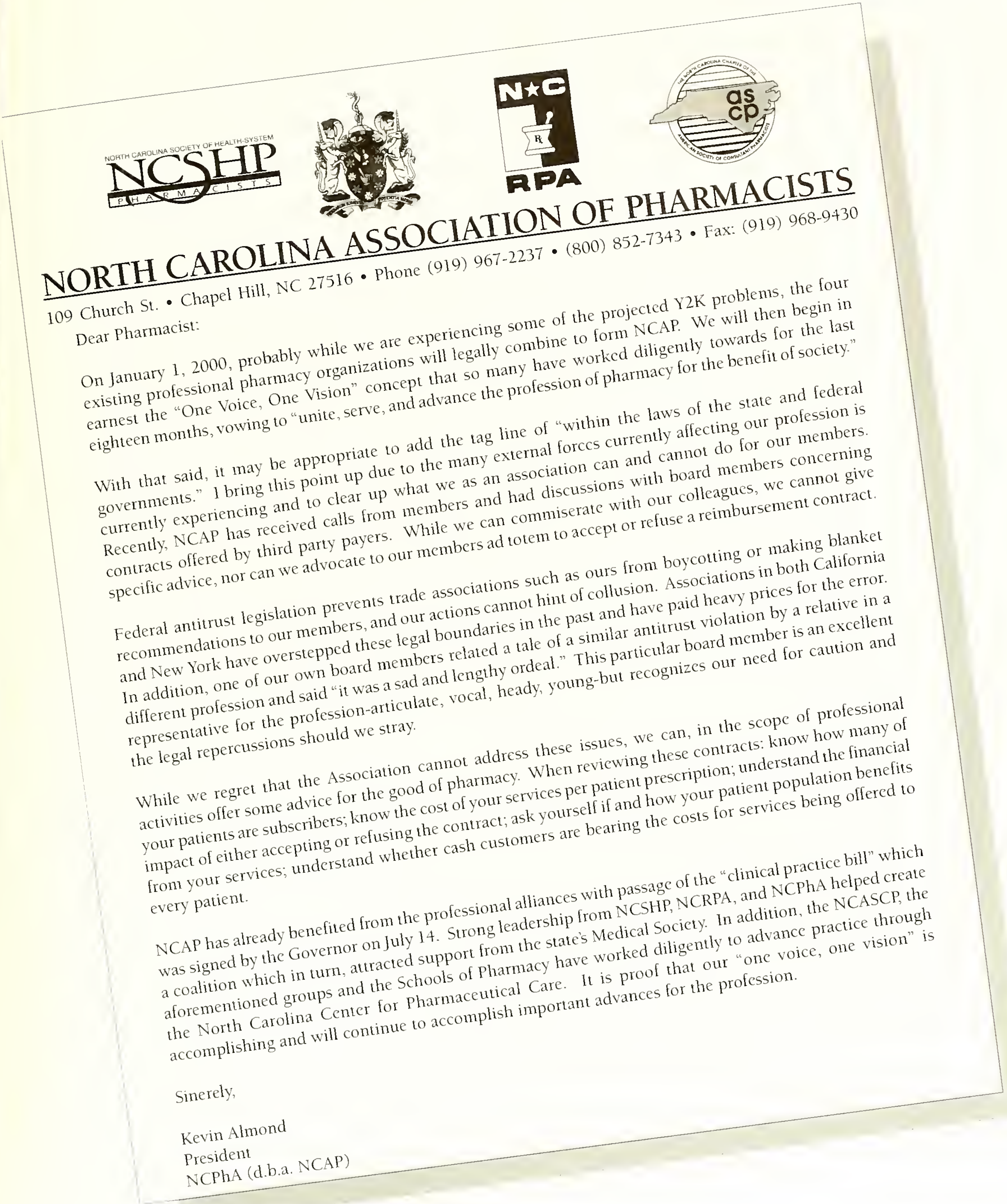
Why now? In 1994 NCSHP and NCPhA leaders formed what became known as the Pharmacy Practice Advancement Committee. From that came the North Carolina Center for Pharmaceutical Care, which created the diabetes demonstration project in Asheville and the unification of all pharmacy organizations in our state. What's new is that in 1999 the profession is again working together and collectively blazing a new path for pharmacy in the 21st century.

Few people realize that it was pharmacists from across the state who created the first pharmacy organization in North Carolina in Raleigh in 1880. This group became our professional association, which then created the Board of Pharmacy, the UNC School of Pharmacy and the Pharmacy Practice Act. It is important to note that the professional association came first and fostered the development of the board, the school and the law.

The next item on the NCAP professional agenda is the creation of credentialing standards for Clinical Pharmacist Practitioners. Many people have been looking to the Board, the schools, and the Legislature to set these standards, but this is the wrong path. History teaches us that it is the profession's responsibility to advance practice. The standards for Clinical Pharmacist Practitioners must come from the Association.

NCAP is taking the lead in working with the Medical Society to define standards for credentialing Clinical Pharmacist Practitioners. Local efforts in Asheville and Greensboro have resulted in pharmacist certificate training programs, networks of clinical pharmacist practitioners for disease management and reimbursement for patient care services. These local programs preceded the Mississippi initiative, the NABP disease management exams, and standardized programs from the schools of pharmacy. In fact, these local programs are now used as models for state and national efforts. On the state level, NCAP is working with NCCPC, AHEC and the Schools of Pharmacy to standardize certificate training programs, the Board of Pharmacy on pre-requisites for the NABP disease management tests, and the Medical Society on the Clinical Pharmacist Practitioner Act. At the national level, NCAP is represented on the Standards Advisory Board for the NABP exams and has had input into the ACPE standards for certificate training and the North Carolina Clinical Practitioner legislation is looked to as a model for other states to use to advance practice.

NCAP is the crucible where we can form pharmacy's vision for the next millennium. With NCAP, we have a unified voice for pharmacy in North Carolina, because NCAP is all of us working together to develop new practice models for pharmacy's future. Many pharmacists from across the state have been involved in these local, state and national efforts, and everyone has shared their time, talent and energy for the collective benefit of our profession. Please do your part like those pharmacists did in Raleigh in 1880. Work selflessly with other pharmacists across the state to establish the new clinical standards for our profession.◉



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Dear Pharmacist:

On January 1, 2000, probably while we are experiencing some of the projected Y2K problems, the four existing professional pharmacy organizations will legally combine to form NCAP. We will then begin in earnest the "One Voice, One Vision" concept that so many have worked diligently towards for the last eighteen months, vowing to "unite, serve, and advance the profession of pharmacy for the benefit of society."

With that said, it may be appropriate to add the tag line of "within the laws of the state and federal governments." I bring this point up due to the many external forces currently affecting our profession is currently experiencing and to clear up what we as an association can and cannot do for our members. Recently, NCAP has received calls from members and had discussions with board members concerning contracts offered by third party payers. While we can commiserate with our colleagues, we cannot give specific advice, nor can we advocate to our members ad totem to accept or refuse a reimbursement contract.

Federal antitrust legislation prevents trade associations such as ours from boycotting or making blanket recommendations to our members, and our actions cannot hint of collusion. Associations in both California and New York have overstepped these legal boundaries in the past and have paid heavy prices for the error. In addition, one of our own board members related a tale of a similar antitrust violation by a relative in a different profession and said "it was a sad and lengthy ordeal." This particular board member is an excellent representative for the profession-articulate, vocal, heady, young-but recognizes our need for caution and the legal repercussions should we stray.

While we regret that the Association cannot address these issues, we can, in the scope of professional activities offer some advice for the good of pharmacy. When reviewing these contracts: know how many of your patients are subscribers; know the cost of your services per patient prescription; understand the financial impact of either accepting or refusing the contract; ask yourself if and how your patient population benefits from your services; understand whether cash customers are bearing the costs for services being offered to every patient.

NCAP has already benefited from the professional alliances with passage of the "clinical practice bill" which was signed by the Governor on July 14. Strong leadership from NCSHP, NCRPA, and NCPhA helped create a coalition which in turn, attracted support from the state's Medical Society. In addition, the NCASCP, the aforementioned groups and the Schools of Pharmacy have worked diligently to advance practice through the North Carolina Center for Pharmaceutical Care. It is proof that our "one voice, one vision" is accomplishing and will continue to accomplish important advances for the profession.

Sinerely,

Kevin Almond
President
NCPhA (d.b.a. NCAP)

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# NCAP WOULD LIKE TO WELCOME THE FOLLOWING NEW MEMBERS:

Mary Anthony of Winston- Salem
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Jerry Beamer of Lexington
George Bender of Fayetteville
Randy Bitikofer of Waynesville
Randall Bowling of Durham
Gary Bowman of Oxford
Aaron Brentzel of Matthews
Ben Brooks of Loganville, GA
Abdulfattah Budayr of Cary
Claude Burney of Raleigh
Terri Cardwell of Clemmons
Charles Carter of Lumberton
Robert Clevenger III of Charlotte
James Coleman of Melbourne, FL
Mary Cooke of Greensboro
William Coppedge of Asheville
John Crawford of Asheville
Pamela Criss of Cornelius
Mary Ellen Davis of Sylva
Donna Durfee of Charlotte
Jane Edwards of Boydton, VA
Sandra English of Palm Beach Gardens, FL
Carla Ferrara of Charlotte
James Floyd of Mullins, SC
Gina Genevro of Matthews
Dina Goodson of Fayetteville
Christopher Gordon of Greensboro
Holly Griffin of Morgantown, WV
Mindy Hart of Greensboro
Ginger Hartsoe of Winston-Salem
Lewis Holder, Jr. of Hickory
Nae Hong of Corona, CA
Joel James of Chapel Hill
Karen Kelley of Young Harris, GA
Johnny King of Greensboro
George Kirkpatrick, Jr. of Midlothian, VA
Emmitt Knight of Matthews
Virginia Knight of Matthews
Holly LaRoque of Kinston
Virginia Lawing of Chesnee, SC
Richard Mack of Lenoir
Sarah Melton of Fayetteville
Jean Mesaros of Danville,VA
Thomas Nola of Wilmington
Josephine Polhemus of Gastonia
Kader Ramsey, Jr. of Gastonia
Margaret Ramsey of Gastonia
Katina Rice of Winston Salem
Belinda Riddle of Bessemer City
Susan Scott of Lewisville
Richard Self of Charlottesville, VA
Sherry Denise Sims of Highlands
Edward Smith of Ortonville, MI
Paul Smith of Graham
Ronald Smith of Burlington
David Spain of Raleigh
Sylvia Stafford of Benson
Beth Strauss of Wilmington
Marie Taylor of Columbia, SC
Edward Thomas IV of Glen Allen, VA
Constance Upshaw of Raleigh
Susan Van Tassel of Asheville
George Walker of Virginia Beach, VA
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# PHARMACY GRADUATION AT CAMPBELL & UNC

*While graduation is the happiest of times, not everyone could make it to Carolina's May 16th graduation, which sent 100 new pharmacists into the world, or Campbell's ceremony on May 9, which sent 87. So as a commemeration of those special days, the Journal of Pharmacy is reprinting highlights from the graduation speeches from both schools.*

## Welcoming Comments, Dean William Campbell, UNC School of Pharmacy

While people are settling, let me add my welcome to this day of celebration. Every graduation day is unique, but today's is doubly exceptional. It is the last graduation of the 20th century, and so it will be another 1,000 years before we have another ceremony under these same circumstances. Now, I have always thought of this group of graduates as a unique group, but a one in 1,000 year group? THAT'S unique! More importantly, it is unique because the dreams, aspirations, hard work, and assistance of many people have come together in this time and place. As the curtain closes on the 20th century, another curtain opens to these graduates. The curtains are opening to what must be the greatest time of opportunity and demand for their talents of any group in history. In fact, to the graduates I say, you might want to thank your parents not just for birth, but for the timing of your birth. Measured by the positions and salaries being offered, it is a bidding war out there for your talents. (Indeed, I am concerned that faculty will discover the salaries being offered these graduates and we will soon have no faculty.)

The pomp and circumstance of graduation is one of the hallmarks of the University. Lest you in the audience think we dress like this every day; we don't. The reason we are in robes and gowns is to mark the solemn responsibility of every person who is here today.

First, the dean— representing the Chancellor— represents the origin of authority in the University. A University's authority stems from the church, partly because the church was the guardian of doctrine, and partly because only the clerics could read and write in the Middle Ages. So my role in antiquity was to represent the authority of the institution, in those days the pope, but in the modern world to represent the authority of the University of North Carolina.

*see Campbell on page 28*

## UNC Commencement Address
### James McAllister III
### Director of Pharmacy, UNC Hospitals

I would like to focus for a few minutes on an article entitled, "Searching for the Soul of Pharmacy" written two years ago by Dr. William Zellmer, Deputy Executive Vice-President of my pharmacy association, ASHP. I believe it is one of the most important articles ever written about the profession of pharmacy. It is provocative, if not shocking and challenging, if not motivational.

The focus of Bill's article is that the soul or character of individual pharmacists must be nourished in order to save pharmacy as a health profession, and presumes that we alone can change our profession.

Dr. Zellmer's metaphorical approach to encouraging pharmacists to assume more active roles in "saving" our profession should be required reading for all pharmacists. Since you have completed your formal studies, I have provided a copy of this article at the exits for each family who, I think, will find it interesting reading. Since they have made a significant investment in your education and are hopeful that it pays off, I would encourage parents (and spouses) and new graduates to discuss the paper when they're together this Summer.

In his treatise, Bill is constructively critical of many facets of the health care delivery system and pharmacists who work within it. He characterizes health care systems and networks as rigid and impersonal, instead of caring. He suggests that private sector health care reform and managed care are polite terms for the rape of the health care system created decades ago.

He makes a good case for the quality of care being reduced without a commensurate reduction in cost. Dr. Zellmer challenges society on its apparent denial of the fact that not all Americans have access to quality health care. Bill criticizes hospital and health care system pharmacists, as well as pharmacists practicing within the community, suggesting that many of us are too preoccupied with the business of health care and that the chaotic change around us has blurred our focus on our primary obligations to patients. He calls for us to be brave and take risks; suggesting pharmacists' interests in their patients may need to take precedence over the interests of their employer.

While I'm not sure I agree with Bill ... that the profession needs to be "saved" ... I heartily agree with much of what he says, including that we are confronted with priceless opportunities to demonstrate our responsibility to patients and to reinforce that allegiance every day of our lives as we practice this profession.

This may take many forms and includes ensuring patients make good transitions from the community into the hospital, and from the hospital back into the community, and from one health care provider to another.

Almost 10 years ago, I suggested that pharmacists should consider the

*see McAllister on page 29*

# Campbell University Keynote Address

**Wm. Whitaker Moose**
**President,**
**National Community Pharmacists Association**

I consider it a great honor to speak to this 1999 hooding ceremony at Campbell University. It was nearly 40 years ago that I listened to my own commencement address. The truth is, I cannot remember anything at all about the speaker/or what he said. Then nearly 20 years later I gave a commencement address at Chapel Hill. All I can remember from that experience is the horrible blue and white checked suit with bell-bottoms that I wore, some small town jokes I told, and I believe I told students to go out and do good things. The point of all of this is that you, nor I, will long remember what is said today, but you will remember this day.

This is a great moment in your life. As our 20th President James Garfield said in 1881, "Next in importance to freedom and justice is education, without which neither freedom nor justice can be permanently maintained." This is a milestone, a high water mark, a critical point in time, an accomplishment worthy of note for each and every one of you. Maybe even especially for your parents! Drink it in, cherish it, enlarge it, and indelibly imprint it in your minds; you are joining a wonderful profession-one in which the opportunities have never been greater. A profession that faces 18 million consumers each and every day. A profession that has been chosen as the most trusted and respected profession in America ten times running. So whether you chose to practice community pharmacy, hospital long-term care, research, industry, managed care, or teaching, the opportunities are great and prestige is considerable.

> **"Our profession cannot survive just counting, pouring, licking and sticking. We must be involved in patient outcomes."**

Your education gives you the keys to open many doors, but it also carries substantial responsibility. Professional pride, financial rewards, and self-confidence are just a few of the doors you have opened. But with prosperity and accomplishment comes great responsibility-responsibility to be honest, to truly care about your patients, to be ethical, and to leave the profession a little better than you found it.

Pharmacy has come very far in the past 40 years, but it still has further to go. We pride ourselves on being honest and forthright with our patients, our physicians, and with other pharmacists. I hope as you go to your various areas of work that you will commit yourself to an ethical standard that will not compromise your, or my, professional standing.

We live in a world of rapid social and political change. Sometimes it almost seems like we have double standards. Sometimes it seems that to get ahead you have to compromise your beliefs and convictions. I am here to say you won't have to, and you shouldn't even consider it. Nothing is worth the price of your integrity.

You see, we don't just need graduates who are fine pharmacists, we need graduates who are also fine Americans. Ethics and integrity will never be old fashioned. I read a survey of recent college graduates done several years ago. In the survey they asked many questions, but the one that caught my attention was, "If I had it to do over again, what would I do differently?" Almost 75% of those graduates said two things. One, they would not have compromised some of their feelings and second, they would have taken more time to enjoy special moments and their friends. Ethics, honor, and integrity are tools, like your education, that will serve you well.

You are very special people. Not just because you now have a Pharm. D. degree. And not because you are a graduate of a school of pharmacy that has far better passing rate of the National Board of Pharmacy examination than most schools of pharmacy. And not just because you have shared the cultural experiences of Buies Creek, or as some say, graduated from UCLA - the University of Campbell between Lillington and Angier. You are special because you have graduated from a Christian University that imparts that Christian ethic throughout every phase of life. You yourself might not be Christian, but every class, every course, every encounter in your education process has had that Christian ethic in its background. No matter where you go, or what you do, that experience will be with you. It is to be honored and preserved. It is what makes you special. No one other than yourself can take it away from you.

I would remiss if I didn't emphasize that our profession, while full of opportunities, also has many obstacles facing it. Issues like the dilemma of a health system that can do almost anything, but cannot afford to everything for everyone. A health system where decisions are made by the insurance industry rather than by health care providers. A system where reimbursements seem to continue to shrink, and the pharmaceutical product is treated as a commodity.

One thing I believe is certain for you and for pharmacy in the future. For pharmacy to succeed and retain its place as the most respected profession, we will have to truly become involved with complete patient care. Out profession cannot survive just counting, pouring, licking and sticking. We must be involved in patient outcomes.

The new millennium is full of opportunities for pharmacy. More and more breakthrough medicines are on the horizon, and more medicines will be dispensed. A disproportionate number of those medicines will be administered to our rapidly growing senior population. Seniors take three to four times as many medicines as any other group, and they require the hands-on care and attention of their pharmacists.

Pharmacists today are monitoring the care of diabetic patients, screening patients for osteoporosis and high blood pressure, helping them control their cholesterol levels, and administering immunizations. Many of these pharmacists are becoming certified in specific areas of practice, and are being paid for providing these patient care services.

That is what awaits you in the new millennium-an opportunity to fulfill the enormous promise of pharmacist.◉

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# ORLISTAT (XENICAL®)

## A New Alternative for Obesity Management

by: Susanne Lee, PharmD

The prevalence of obesity in the United States increased dramatically from 1960 to 1991 and continues to be a major health concern today.[1] Obesity has been identified as an important risk factor for diabetes[2] and cardiovascular disease,[3] causing significant morbidity and mortality.[3,4,5] Weight-loss medications offer clinicians an adjunct to dietary restriction and lifestyle modification to manage this increasingly common and challenging therapeutic dilemma.[6]

The most recent medication to be approved by the Food and Drug Administration for obesity management is Orlistat (Xenical®, Roche Pharmaceuticals). Orlistat was approved in May 1999 for weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. Additionally, Orlistat is indicated to reduce the risk for weight regain after prior weight loss. Appropriate patients for Orlistat therapy are obese and have a body mass index (BMI) of $\geq 30$ kg/m$^2$ or $\geq 27$ kg/m$^2$ when other risk factors for cardiovascular disease (eg, hyperlipidemia, hypertension, diabetes) are present.[7]

In contrast to other obesity management medications, Orlistat does not exhibit appetite suppressant effects, rather it binds to and reversibly inhibits gastric and pancreatic lipases in the lumen of the stomach and small intestine. This inhibition prevents the breakdown of dietary trigylcerides into free fatty acids and monoglycerides, thereby preventing triglyceride absorption. Dietary fat absorption is reduced by approximately 30% when Orlistat is taken according to the manufacturer's recommendations. The resultant caloric deficit is responsible for the weight control benefits.[7]

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Following oral administration, Orlistat is minimally absorbed; however, systemic absorption is not necessary for therapeutic activity. Approximately 50% of the parent compound is metabolized in the wall of the gastrointestinal tract to two pharmacologically insignificant metabolites, M1 and M3. Orlistat is excreted mainly in the feces and bile with a half-life of 1 to 2 hours. Due to the relative lack of absorption, special populations (e.g., geriatric) have not been studied. The manufacturer recommended dose of Orlistat is 120 mg orally three times daily (TID) during or up to one hour after each fat containing meal. If a meal is skipped or contains no fat, the Orlistat dose should be omitted.[7]

The efficacy of orlistat in inducing weight loss and preventing weight regain has been assessed in otherwise healthy obese patients.[6] A randomized, double-blind, multi-center study compared orlistat to placebo over 2 years. Following a 4-week lead-in phase designed to assess compliance, 688 of 743 patients were stratified according to the amount of weight loss in the lead-in phase and randomized to receive either orlistat 120 mg or placebo TID for 1 year. Patients were instructed to adhere to a reduced calorie diet containing approximately 30% of calories from fat. At the beginning of the second year of study, patients were reassigned to receive either Orlistat or placebo in an effort to assess weight regain. During this second phase, patients were instructed to adhere to a weight maintenance diet. The primary outcomes measured were weight reduction in the first year and weight maintenance in the second year. At the end of the first year, the average reduction in weight was 10.3 kg in the patients receiving orlistat and 6.1 kg in the patients receiving placebo. This was representative of a 68% greater weight loss in the treatment group ($p<0.001$). At the end of the second year, patients initially treated with placebo who switched to Orlistat lost more weight than patients continuing on placebo ($p<0.001$). Those initially taking Orlistat who continued on Orlistat regained less weight than those switching from Orlistat to placebo ($p<0.001$). Alterations in cardiovascular risk factors were also assessed during the study. At the end of the first and second years, significant improvements were noted in total cholesterol and LDL cholesterol independent of weight loss. The authors concluded that Orlistat may be appropriate as an adjunct to dietary restrictions for the long-term treatment of obesity.[6]

In a similar two-phase trial, 892 patients received either placebo or Orlistat 120 mg TID in conjunction with a controlled diet for 1 year.[3] In the second phase, patients originally receiving

see Orlistat on page 26

# PHARMACISTS ADVOCATE PASSAGE OF BONE MASS MEASUREMENT BILL

**by: Rebecca Chater**

As Osteoporosis Awareness Day in the North Carolina Legislature, May 5th was an exciting day for NC pharmacists. Several practitioners and students came together to inform legislators about the expanded role of the pharmacist in the prevention, detection, and treatment of osteoporosis and to encourage their support in passage of the Bone Mass Measurement Bill under consideration by the NC Senate at the time of this publication.

Participating in the event were: Rebecca Chater, R.Ph., M.P.H., shared faculty member of the UNC School of Pharmacy and Kerr Drug, Inc. and Coodinator of the Kerr/UNC Enhanced Pharmaceutical Care Center (EPCC); clerkship students of the EPCC—Susan Ganther, P2, Campbell University, and Jessica Visco, PY3, UNC; Mongthuong Tran, PY4 student, UNC, and independent study student of the EPCC; Tom Jones, R.Ph., independent owner of Tom Jones Pharmacy in Garner; and Ann Scates, Pharm.D., Drug Information Specialist, Duke University Medical Center.

According the Rebecca Chater, "legislators and fellow healthcare professionals participating in the event responded quite favorably to community pharmacist involvement in helping patients understand their risk, strategies for prevention, and treatment options associated with osteoporosis. Patients participating in our educational workshops and BMD testing at the EPCC have consistently remarked on the great quality, cost-effectiveness, and access to our service. Overwhelmingly, our patients have expressed their belief that participation in this type of activity is a perfect role for the community pharmacist."

The Bone Mass Measurement Bill, which has already been ratified by the NC House (House Bill 314) and approved by the Insurance Commission, would require private insurers to cover the cost of bone mineral density (BMD) testing for patients meeting specific risk criteria. This comes on the heels of the recent Medicare Bone Mass Measurement Coverage Act, effective July 1, 1998, which mandates Medicare payment for all BMD testing performed on at risk patients regardless of the test result. At publication, the Bill is approaching its final hurdle—passage by the Senate.

Osteoporosis is responsible for 1.5 million fractures each year, at an estimated cost of $18 billion. Alarmingly, the National Osteoporosis Foundation (NOF) and the World Health Organization (WHO) project the number of women affected by osteoporosis to double by the year 2020. Community pharmacist involvement in prevention, detection, and treatment of fracture risk is highly valuable to the public health. A favorable vote by the Senate would certainly have significant positive impact on provision of these services by community pharmacists.◉

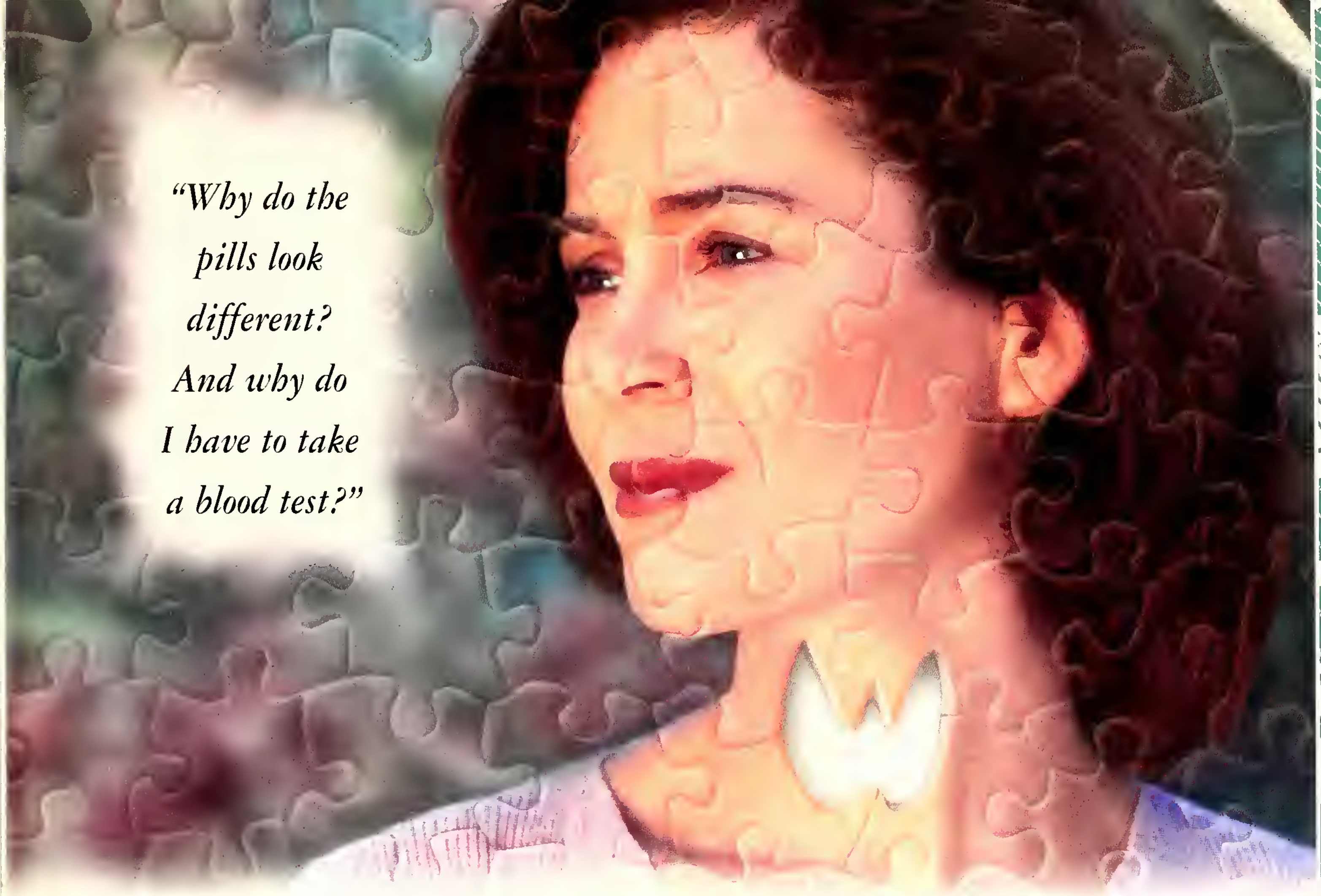
About the Author:

*Rebecca Chater, R.Ph., M.P.H. is the coordinator of the Kerr Drug/UNC Enhanced Pharmaceutical Care Center and is a visiting Clinical Assistant Professor at the UNC School of Pharmacy. She can be reached at (800) 494 3053 x440 or kerr-epcc@mindspring.com.*

# Changes to Continuing Education

**In order to better serve our members, the Carolina Journal of Pharmacy will be mailing a special CE Supplement only to members who request it by August 15. CE will no longer be published in the Journal, leaving more room for news of interest to all readers. As always, Continuning Education is available only to members.**

**Members who would like to be added to the mailing list for CE should contact Teressa Reavis at teressa@ncpharmacists.org or (800) 852-7343.**



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**WARNINGS** Thyroid hormones, either alone or together with other therapeutic agents, should not be used for the treatment of obesity In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

The use of SYNTHROID in the treatment of obesity, either alone or in combination with other drugs, is unjustified. The use of SYNTHROID is also unjustified in the treatment of male or female infertility unless this condition is associated with hypothyroidism.

**PRECAUTIONS General**. SYNTHROID should be used with caution in patients with cardiovascular disorders, including angina, coronary artery disease, and hypertension, and in the elderly who have a greater likelihood of occult cardiac disease. Concomitant administration of thyroid hormone and sympathomimetic agents to patients with coronary artery disease may increase the risk of coronary insufficiency

Use of SYNTHROID in patients with concomitant diabetes mellitus, diabetes insipidus or adrenal cortical insufficiency may aggravate the intensity of their symptoms. Appropriate adjustments of the various therapeutic measures directed at these concomitant endocrine diseases may therefore be required. Treatment of myxedema coma may require simultaneous administration of glucocorticoids (see **DOSAGE AND ADMINISTRATION**).

$T_4$ enhances the response to anticoagulant therapy Prothrombin time should be closely monitored in patients taking both SYNTHROID and oral anticoagulants, and the dosage of anticoagulant adjusted accordingly

Seizures have been reported rarely in association with the initiation of levothyroxine sodium therapy, and may be related to the effect of thyroid hormone on seizure threshold

Lithium blocks the TSH-mediated release of $T_4$ and $T_3$. Thyroid function should therefore be carefully monitored during lithium initiation, stabilization, and maintenance. If hypothyroidism occurs during lithium treatment, a higher than usual SYNTHROID dose may be required

**Laboratory Tests** Treatment of patients with SYNTHROID requires periodic assessment of adequacy of titration by appropriate laboratory tests and clinical evaluation. Selection of appropriate tests for the diagnosis and management of thyroid disorders depends on patient variables such as presenting signs and symptoms, pregnancy, and concomitant medications. A combination of sensitive TSH assay and free $T_4$ estimate (free $T_4$, free $T_4$ index) are recommended to confirm a diagnosis of thyroid disease. Normal ranges for these parameters are age-specific in newborns and younger children.

TSH alone or initially may be useful for thyroid disease screening and for monitoring therapy for primary hypothyroidism as a linear inverse correlation exists between serum TSH and free $T_4$ Measurement of total serum $T_4$ and $T_3$, resin $T_3$ uptake, and free $T_3$ concentrations may also be useful. Antithyroid microsomal antibodies are an indicator of autoimmune thyroid disease The presence of positive microsomal antibodies in an euthyroid patient is a major risk factor for the future development of hypothyroidism An elevated serum TSH in the presence of a normal $T_4$ may indicate subclinical hypothyroidism. Intracellular resistance to thyroid hormone is quite rare, and is suggested by clinical signs and symptoms of hypothyroidism in the presence of high serum $T_4$ levels. Adequacy of SYNTHROID therapy for hypothyroidism of pituitary or hypothalamic origin should be assessed by measuring free $T_4$, which should be maintained in the upper half of the normal range. Measurement of TSH is not a reliable indicator of response to therapy for this condition. Adequacy of SYNTHROID therapy for congenital and acquired pediatric hypothyroidism should be assessed by measuring serum total $T_4$ or free $T_4$, which should be maintained in the upper half of the normal range. In congenital hypothyroidism, normalization of serum TSH levels may lag behind normalization of serum $T_4$ levels by 2 to 3 months or longer. In rare patients serum TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of $T_4$ or free $T_4$

**Drug Interactions** The magnitude and relative clinical importance of the effects noted below are likely to be patient-specific and may vary by such factors as age, gender, race, intercurrent illnesses, dose of either agent, additional concomitant medications, and timing of drug administration Any agent that alters thyroid hormone synthesis, secretion, distribution, effect on target tissues, metabolism, or elimination may alter the optimal therapeutic dose of SYNTHROID.

*Adrenocorticoids*–Metabolic clearance of adrenocorticoids is decreased in hypothyroid patients and increased in hyperthyroid patients, and may therefore change with changing thyroid status

*Amiodarone*–Amiodarone therapy alone can cause hypothyroidism or hyperthyroidism.

*Anticoagulants (oral)*–The hypoprothrombinemic effect of anticoagulants may be potentiated, apparently by increased catabolism of vitamin K-dependent clotting factors.

*Antidiabetic agents (insulin, sulfonylureas)*–Requirements for insulin or oral antidiabetic agents may be reduced in hypothyroid patients with diabetes mellitus, and may subsequently increase with the initiation of thyroid hormone replacement therapy

β-*adrenergic blocking agents*–Actions of some beta-blocking agents may be impaired when hypothyroid patients become euthyroid

*Cytokines (interferon, interleukin)*–Cytokines have been reported to induce both hyperthyroidism and hypothyroidism.

*Digitalis glycosides*–Therapeutic effects of digitalis glycosides may be reduced. Serum digitalis levels may be decreased in hyperthyroidism or when a hypothyroid patient becomes euthyroid

*Ketamine*–Marked hypertension and tachycardia have been reported in association with concomitant administration of levothyroxine sodium and ketamine

*Maprotiline*–Risk of cardiac arrhythmias may increase.

*Sodium iodide ($^{123}I$ and $^{131}I$), sodium pertechnetate Tc99m*–Uptake of radiolabeled ions may be decreased

*Somatrem/somatropin*—Excessive concurrent use of thyroid hormone may accelerate epiphyseal closure. Untreated hypothyroidism may interfere with the growth response to somatrem or somatropin

*Theophylline*—Theophylline clearance may decrease in hypothyroid patients and return toward normal when a euthyroid state is achieved

*Tricyclic antidepressants*—Concurrent use may increase the therapeutic and toxic effects of both drugs, possibly due to increased catecholamine sensitivity. Onset of action of tricyclics may be accelerated.

*Sympathomimetic agents*—Possible increased risk of coronary insufficiency in patients with coronary artery disease.

**Laboratory Test Interactions** A number of drugs or moieties are known to alter serum levels of TSH, $T_4$ and $T_3$ and may thereby influence the interpretation of laboratory tests of thyroid function (see **Drug Interactions**)

1. Changes in TBG concentration should be taken into consideration when interpreting $T_4$ and $T_3$ values. Drugs such as estrogens and estrogen-containing oral contraceptives increase TBG concentrations. TBG concentrations may also be increased during pregnancy and in infectious hepatitis. Decreases in TBG concentrations are observed in nephrosis, acromegaly, and after androgen or corticosteroid therapy. Familial hyper- or hypo-thyroxine-binding-globulinemias have been described The incidence of TBG deficiency is approximately 1 in 9000. Certain drugs such as salicylates inhibit the protein-binding of $T_4$. In such cases, the unbound (free) hormone should be measured Alternatively, an indirect measure of free thyroxine, such as the $FT_4I$ may be used.

2. Medicinal or dietary iodine interferes with *in vivo* tests of radioiodine uptake, producing low uptakes which may not indicate a true decrease in hormone synthesis

3 Persistent clinical and laboratory evidence of hypothyroidism despite an adequate replacement dose suggests either poor patient compliance impaired absorption, drug interactions, or decreased potency of the preparation due to improper storage.

**Carcinogenesis, Mutagenesis, and Impairment of Fertility:** Although animal studies to determine the mutagenic or carcinogenic potential of thyroid hormones have not been performed, synthetic $T_4$ is identical to that produced by the human thyroid gland. A reported association between prolonged thyroid hormone therapy and breast cancer has not been confirmed and patients receiving levothyroxine sodium for established indications should not discontinue therapy

**Pregnancy**: Pregnancy Category A. Studies in pregnant women have not shown that levothyroxine sodium increases the risk of fetal abnormalities if administered during pregnancy If levothyroxine sodium is used during pregnancy, the possibility of fetal harm appears remote Because studies cannot rule out the possibility of harm, levothyroxine sodium should be used during pregnancy only if clearly needed

Thyroid hormones cross the placental barrier to some extent. $T_4$ levels in the cord blood of athyroid fetuses have been shown to be about one-third of maternal levels. Nevertheless, maternal-fetal transfer of $T_4$ may not prevent *in utero* hypothyroidism.

Hypothyroidism during pregnancy is associated with a higher rate of complications, including spontaneous abortion and preeclampsia, and has been reported to have an adverse effect on fetal and childhood development. On the basis of current knowledge, SYNTHROID (levothyroxine sodium, USP) should therefore not be discontinued during pregnancy, and hypothyroidism diagnosed during pregnancy should be treated Studies have shown that during pregnancy $T_4$ concentrations may decrease and TSH concentrations may increase to values outside normal ranges. Postpartum values are similar to preconception values. Elevations in TSH may occur as early as 4 weeks gestation.

Pregnant women who are maintained on SYNTHROID should have their TSH measured periodically An elevated TSH should be corrected by an increase in SYNTHROID dose After pregnancy, the dose can be decreased to the optimal preconception dose

**Nursing Mothers** Minimal amounts of thyroid hormones are excreted in human milk Thyroid hormones are not associated with serious adverse reactions and do not have known tumorigenic potential. While caution should be exercised when SYNTHROID is administered to a nursing woman, adequate replacement doses of levothyroxine sodium are generally needed to maintain normal lactation

**Pediatric Use: Congenital hypothyroidism** Rapid restoration of normal serum $T_4$ concentrations is essential for preventing the deleterious effects of neonatal thyroid hormone deficiency on intelligence, as well as on overall growth and development. SYNTHROID should be initiated immediately upon diagnosis, and is generally continued for life. The goal of therapy is to maintain the serum total $T_4$ or $FT_4$ in the upper half of the normal range and serum TSH in the normal range.

An initial starting dose of 10 to 15 mcg/kg/day (ages 0-3 months) will generally increase serum $T_4$ concentrations to the upper half of the normal range in less than 3 weeks. Clinical assessment of growth and development and thyroid status should be monitored frequently In most cases, the dose of SYNTHROID per body weight will decrease gradually as the patient grows through infancy and childhood (see Table). Prolonged use of large doses in infants may be associated with later behavior problems.

Thyroid function tests (serum total $T_4$ or $FT_4$ and TSH) should be monitored closely and used to determine the adequacy of SYNTHROID therapy Normalization of serum $T_4$ levels is usually followed by a rapid decline of TSH levels. Nevertheless, normalization of TSH may lag behind normalization of $T_4$ levels by 2 to 3 months or longer The relative elevation of serum TSH is more marked during the early months of therapy, but can persist to some degree throughout life In rare patients TSH remains relatively elevated despite clinical euthyroidism and age-specific normal levels of total $T_4$ or $FT_4$ Increasing the SYNTHROID dosage to suppress TSH into the normal range may result in overtreatment, with an elevated serum $T_4$ level and clinical features of hyperthyroidism, including irritability, increased appetite with diarrhea, and sleeplessness Another risk of prolonged overtreatment in infants is premature cranial synostosis.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected Levothyroxine therapy may be interrupted for 30 days after 3 years of age and serum measurement of T4 and TSH levels obtained. If $T_4$ is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted. If $T_4$ and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted

**Acquired hypothyroidism.** The initial dose of SYNTHROID varies with age and body weight, and should be adjusted to maintain serum total $T_4$ or free $T_4$ levels in the upper half of the normal range. In general, in the absence of overriding clinical concerns, children should be started on a full replacement dose. Children with underlying heart disease should be started at lower doses, with careful upward titration. Children with severe, long-standing hypothyroidism may also be started on a lower initial dose with upward titration in an attempt to avoid premature closure of epiphyses The recommended dose per body weight decreases with age (see Table).

Treated children may resume growth at a rate greater than normal (period of transient catch-up growth). In some cases catch-up growth may be adequate to normalize growth; however, in children with severe and prolonged hypothyroidism, adult height may be reduced. Excessive thyroxine replacement may initiate accelerated bone maturation resulting in disproportionate advancement in skeletal age and shortened adult stature.

Assessment of permanence of hypothyroidism may be done when transient hypothyroidism is suspected. Levothyroxine therapy may be interrupted for 30 days and serum measurement of $T_4$ and TSH levels obtained. If $T_4$ is low and the TSH level is elevated, permanent hypothyroidism is confirmed and therapy should be re-instituted If $T_4$ and TSH remain in the normal range, a presumptive diagnosis of transient hypothyroidism can be made. In this instance, continued clinical monitoring and periodic reevaluation of thyroid function may be warranted

**ADVERSE REACTIONS**. Adverse reactions other than those indicative of thyrotoxicosis as a result of therapeutic overdosage, either initially or during the maintenance periods, are rare (see **OVERDOSAGE**). Craniosynostosis has been associated with iatrogenic hyperthyroidism in infants receiving thyroid hormone replacement therapy Inadequate doses of SYNTHROID may produce or fail to resolve symptoms of hypothyroidism. Hypersensitivity reactions to the product excipients, such as rash and urticaria, may occur. Partial hair loss may occur during the initial months of therapy, but is generally transient The incidence of continued hair loss is unknown. Pseudotumor cerebri has been reported in pediatric patients receiving thyroid hormone replacement therapy

**OVERDOSAGE: Signs and Symptoms:** Excessive doses of SYNTHROID result in a hypermetabolic state indistinguishable from thyrotoxicosis of endogenous origin. Signs and symptoms of thyrotoxicosis include weight loss, increased appetite, palpitations, nervousness, diarrhea, abdominal cramps, sweating, tachycardia, increased pulse and blood pressure, cardiac arrhythmias, tremors, insomnia, heat intolerance, fever, and menstrual irregularities Symptoms are not always evident or may not appear until several days after ingestion.

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# NORTH CAROLINA:
# A Leader in Managing Asthma

by: Philip T. Rodgers & Roy A. Pleasants

Asthma is a very common disease in the US; there are about 15 million people in the US with asthma, but the actual number is higher because of under-recognition of the disease. Up to half of these patients are younger than 18 years-old; although, in NC there may be a higher percentage of adult asthmatics. Asthma is a disease that generally responds well to medical interventions such as drug therapy and avoidance of triggers. In some patients, their quality of life improves tremendously with appropriate interventions.

Much has occurred in the US with regards to optimizing care for asthma patients in the 1990's. In response to the increasing prevalence and mortality of asthma since the 1980s, the National Asthma Expert Panel was formed, and subsequently guidelines were published for managing asthma in 1991 and were updated in 1997. There have been a number of comprehensive community efforts throughout the US (e.g. Atlanta, Baltimore) targeted towards better management of asthma. These communities (or cities) use a variety of different models based on their unique needs and resources. North Carolina has been a leader in both local and statewide asthma initiatives over the last several years.

Local asthma initiatives have been undertaken in Greenville, Durham County, and Asheville. Each of these used a different approach depending on community resources in optimizing management of asthma. In Asheville, an asthma educational center was formed and community pharmacists are involved in assisting in the care of certain asthmatic patients. Multidisciplinary partnerships have been formed in the Durham County Asthma Coalition. This effort began about two years ago and has included healthcare practitioners (community and hospital pharmacists, physicians, nurse practitioners, school nurses, and respiratory therapists among others) and other professionals. In this Coalition, pharmacists received intensive educational efforts through an Asthma Certificate Program. Physicians, nurses, and nurse practitioners received in-practice educational programs. About 150 asthma patients attended a community Asthma Day to learn more about the disease and its treatment. Bilingual, low-reading level educational materials are being developed for patients and healthcare providers and will be distributed soon. In addition, the Medicaid system is North Carolina is supporting demonstration projects, Carolina Access II and III. Access II is underway in a small number of counties (e.g. Guilford, Durham) to look at different models to improve care of asthma patients.

There are also two statewide asthma initiatives currently underway: the North Carolina Childhood Asthma Initiative Taskforce and the North Carolina Asthma Board. Both of these groups include a variety of healthcare providers (including pharmacists), government employees (e.g. epidemiologists), and pharmaceutical industry representatives. The Childhood Initiative currently has several goals at present: education for healthcare providers, environmental interventions, improving medical management, and promoting and supporting local asthma coalitions. Plans include: utilizing local environmental health specialists from health departments for home assessments to identify asthma triggers, providing seed funds for the formation of local asthma coalitions, providing intensive educational experiences for primary care physicians, and completion of a large epidemiological study of the prevalence of asthma in school age children in N.C. There are some very real opportunities for interested pharmacists to initiate or get involved in local coalitions. The Childhood Initiative will be holding regional meetings sometime in August or September in the Western, and Piedmont, and Eastern parts of the state for persons interested in starting local asthma initiatives. Currently, one meeting has been scheduled at Duke University Medical Center for the Piedmont Region on August 12, 1999. Pharmacists are welcome and encouraged to attend one of these sessions.

The N.C. Asthma Board is also substantially involved in promoting the optimal management of asthma. The Board is currently focused on supporting a healthcare practitioner model that is termed the "Certified Asthma Educator (CAE)." It will likely mirror the existing Certified Diabetes Educator (CDE), which currently counts many pharmacists among their ranks. In order to become a CDE, a healthcare practitioners must have a minimum number of contact hours with diabetic patients and pass an examination. At the present time, it appears highly likely that the American Lung Association will be the national organization that develops and implements the process for the Certified Asthma Educator on a national level. Last February, the N.C. Asthma Board strongly supported quality asthma training programs for healthcare professionals to help train healthcare practitioners to ultimately become CAE's. The Asthma Board is currently providing support for a British asthma training program called the National Asthma and Respiratory Training Center Diploma Program and other quality programs. They have acquired financial support from pharmaceutical industry to train 44 healthcare practitioners in NC including pharmacists in the NARTC program. It is expected that the availability of CAE's in communities could really enhance the management of asthma. You, the pharmacist, can become a CAE in the near future, if you so choose. CDE's are currently reimbursed for their interventions; and it is anticipated that CAE's will also receive payment for their services. It is also possible that opportunities for pharmacists will be available if the Clinical Pharmacy Practitioner law is passed in the 1999 State Legislature. Opportunities for reimbursement for cognitive services may help alleviate some of the financial burdens associated with dispensing of prescriptions.

There have been many clinical studies on the outcomes that pharmacists can have on the asthmatic patient. These appear in both publications and in abstracts from national meetings; a

*see Asthma on page 28*

# North Carolina's 119th Pharmacy Meeting & Convention

Pharmacists from all practice settings — community, hospital and long-term care/consulting – came together in Atlantic Beach for the 119th Annual convention, May 20-22.

Combining education and exhibits with fun times in the sun and on the golf course, the convention was a worthwhile expedition for the 100+ pharmacists who came, many of them with their families.

For the security of pharmacy's future, however, the most important aspect of the convention was the vote to create the North Carolina Association of Pharmacists – NCAP — a new professional organization which will represent all pharmacists in the state.

Outgoing president Keith Elmore (far right) congratulates NCAP's new executive committee members and officers. From the left: new executive committee members Henry Herring, Davie Waggett and Gray Stewart, president-elect Randy Ball and incoming president Kevin Almond.

**by: Macary Weck**

The convention kicked off Thursday afternoon with educational workshops, including a session on herbal and nutriceutical products. Later that evening, NCAP and NCSHP members were honored for their contributions to pharmacy and to their respective organizations at the Awards Program. *(A full listing of awards recipients can be found on page 18)* While enjoying heavy hors d'oeuvres, everyone had the opportunity to meet representatives of the 32 companies that exhibited at our program before dancing the night away at a Shag Dance by the beach.

On Friday morning, history was made at the NCAP and NCSHP business meetings as members officially voted to merge into NCAP. Effective January 1, 2000, North Carolina pharmacists will now be represented by a single, professional organization, the North Carolina Association of Pharmacists (NCAP). (See article on page 19 for more complete coverage).

After such a productive morning, everyone enjoyed lunch with the exhibitors and then ventured outside to enjoy the gorgeous weather by relaxing out on the beach or playing a round of golf in the NCAP tournament.

After working up an appetite all day, the seafood buffet honoring outgoing NCAP President Keith Elmore, hit the spot. At the end of a tremendous day, conventioneers young and old broke out their dancing shoes to shag to the sounds of NCAP member George Willets and his band, The Imitations.

However, if there was one portion of the weekend that NCAP members will want to remember for years to come, it just might be the presentation of the Presidential jacket to incoming NCAP President, Kevin Almond. To lighten up the serious occasion, NCAP member Benny Ridout loaned his trademark bright pink jacket to the Association. When Kevin was presented with Benny's jacket instead of the traditional blue, his face instantly matched the color of the jacket! After a few pictures were taken to capture the moment, the 1999-2000 NCAP officers were also installed. A few more educational sessions wrapped-up the 119th annual meeting for pharmacists in this state.

Additionally, the Woman's Auxiliary attended many of the general programs and also conducted their own business meeting and installation of officers during the convention. Recent graduates from the Campbell and UNC Schools of Pharmacy attended the North Carolina Pharmacy Board Exam Review on Thursday and Friday. NCAP was pleased to coordinate this program for them, and we look forward to their involvement as practitioners in our new Association. On Saturday, many technicians attended the morning educational programs for the pharmacists in addition to their own afternoon program.

There is no doubt that this meeting could not

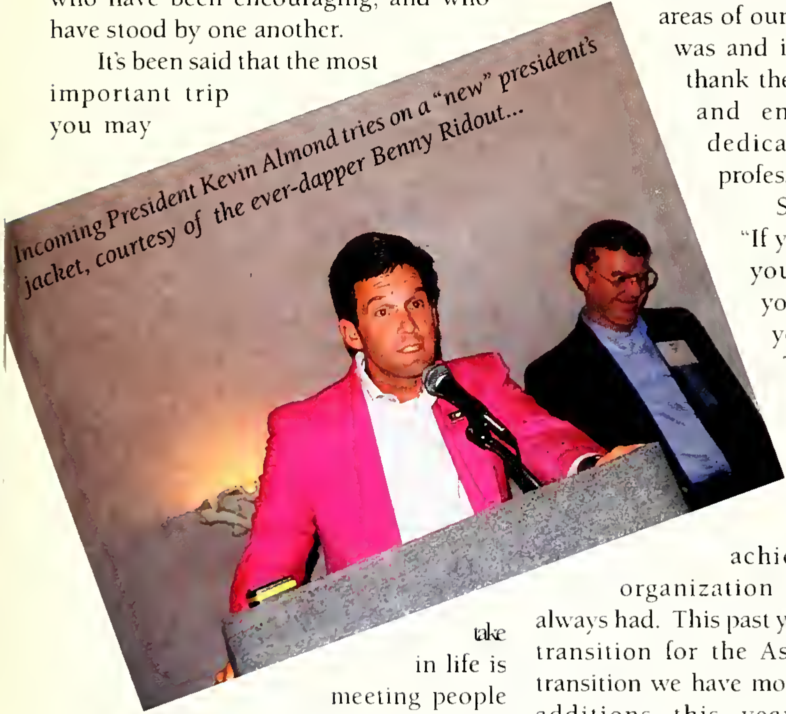
***see Convention on page 18***

NCAP Member George Willets (second from right) led his band the Imitations in a rousing shag dance on Friday night.

# President's Report
## W. Keith Elmore

Almost a year has gone by since I was installed as President of the North Carolina Pharmaceutical Association at our annual meeting in Chapel Hill. The year has gone fast, with many accomplishments. Those of you who were present last year may remember my remarks about the geese, and how they support and encourage one another while in flight, and the lessons we can learn from them. Well, I am happy to tell you that we have as much sense as geese! It has been my privilege to have worked with many dedicated people during the unification process, people who like geese in flight have joined in formation with those headed where they want to go, who share a common direction and sense of community, who have shared leadership, who have been encouraging, and who have stood by one another.

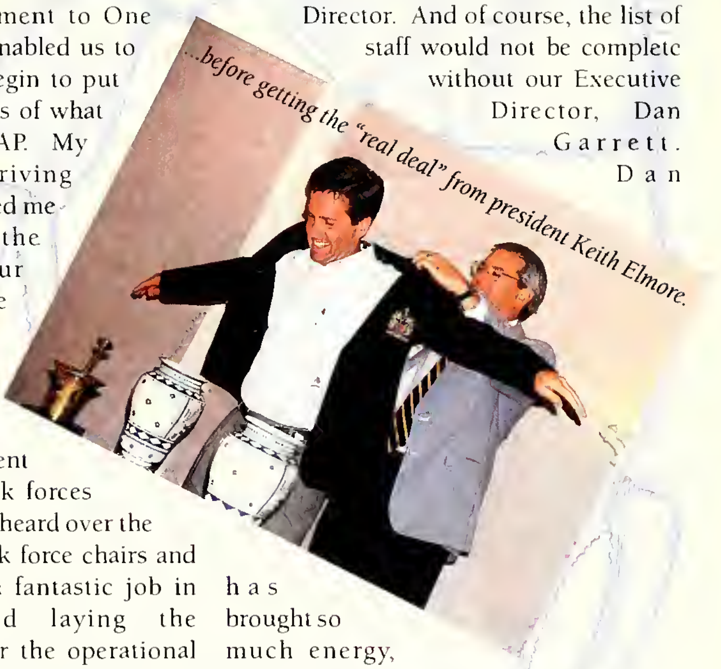
It's been said that the most important trip you may take in life is meeting people halfway. I think I can speak for the other seven members of the Driving Committee when I say that we've done some pretty good traveling this year. Actually, I don't recall many times when we disagreed, and this reaffirmed to me the fact that we would eventually have one organization representing pharmacy in North Carolina.



Incoming President Kevin Almond tries on a "new" president's jacket, courtesy of the ever-dapper Benny Ridout...

One of the most rewarding experiences in my professional life has been working with the leaders of the other three pharmacy organizations on the Driving Committee, with the guidance of Dan Garrett and our facilitator, Liz Becker-Reems. Our commitment to One Voice-One Vision has enabled us to design, organize and begin to put into action the elements of what is now known as NCAP. My service on the Driving Committee has privileged me with a preview of the potential for our Association once we begin to harness the ideas and energies of all pharmacists in the state. Some of this potential is already evident in the work of the task forces whose reports you have heard over the past two days. The task force chairs and members have done a fantastic job in organizing and laying the groundwork for the operational areas of our Association. This was and is a big job, and I thank them all for the time and energy they have dedicated to our profession.

Someone once said: "If you always do what you've always done, you'll always get what you've always got." This is the year that North Carolina's pharmacists have decided that doing things differently will achieve a better organization than what we've always had. This past year has been one of transition for the Association, but in transition we have moved forward. Staff additions this year include Katie McDonough, a CPA who is the Assn's accounting/business manager, Linda Goswick, Executive Assistant, Beth Williams, Director of Pharmaceutical Care Development, and Brent Spodek, Director of Marketing and Communications and Editor of the Carolina Journal of Pharmacy. In addition, Steve Caiola and Fred Eckel are working with the Association to develop and implement post-graduate continuing education and certificate programs. Also, Cathy Jordan is the Meetings Coordinator for the Association, and Teressa Reavis is the Membership Director. And of course, the list of staff would not be complete without our Executive Director, Dan Garrett. Dan has brought so much energy, enthusiasm, and heart to his job. We are truly fortunate to have him working for pharmacy in North Carolina.



...before getting the "real deal" from president Keith Elmore.

Samuel Johnson wrote "The future is purchased by the present," and this year your officers and staff have been busy securing a solid future for your Association. The iMIS software system has been installed and Teressa is establishing a membership database which will enable members and staff to interact in the many areas necessary for an effective organization. A for-profit subsidiary has been formed for the stated purpose of developing and marketing products and services to support health care and which activities will generate non-dues income. We have been active in supporting with money, time, and personal legislative initiatives which, when passed, will advance our profession. We have established a positive working relationship with the Medical Society. For the first time, we have had a full and complete certified audit of the Association's financial position which confirmed the accuracy of our statements and the internal control procedures in place. In these and many other areas, the groundwork has been laid for one professional organization representing all pharmacists in North Carolina.

I want to say what an honor it has been to serve as your President this year. It's a

***see Elmore on page 18***

*Convention, from page 16*

have been made so special without the expertise of the NCAP staff, particularly Cathy Jordan, NCAP Meeting Coordinator, and the assistance of the NCSHP Program Committee/NCAP Continuing Education Task Force. Their months of preparation and planning truly paid off. In addition, we sincerely appreciate the generous support provided by our 1999 Platinum, Gold and Silver Sponsors, other sponsors and convention contributors. The unrestricted educational grants, gifts, services, awards and money supplied by these companies enhanced our convention tremendously, and we look forward to their continued support in the years to come.

Mark your calendars now for the last two state pharmacy meetings of the year: the Pharmacy Practice Seminar, September 11-12, 1999 at the Wilmington Hilton Hotel in Wilmington, NC and the Annual Carolina Seminar, October 6-7, 1999 at the Holiday Inn Four Seasons in Greensboro, NC. See you there!

About the Author:

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# Award Winners

**The Don Blanton Award**
*Whitaker Moose & Bruce Canaday*

**Bowl of Hygeia**
*Gary Glisson*

**The Distinquished Young Pharmacist Award**
*Debra P. Futrell*

**Induction into the 50 Plus Club**
*Ernest Ruffin Anderson*
*Robert Buckner Hall*
*George Daylon Morgan*
*Harley Oneil Benson*
*Clifford Ervin Hemingway*
*Charlotte Borders Plemmons*
*William Cain Braley*
*John Cogdell Hood, Jr.*
*Ralph Peele Rogers, Jr.*
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*Willie Carroll Rose*
*Doris Gilliam Collins*
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*Winfield Penny Rose*
*Oliver Glenn Fleming*
*William Merritt Jordan, Jr.*
*Joseph Carson Southern*
*Evelyn Blanchard Fowler*
*John David Lowe*
*Joseph Kelly Turner, Jr.*
*Leon Irvin Graham*
*Mack Reuben Means*

**The Innovative Pharmacy Practice Award**
*William Horton*

**1998 Continuing Excellence Awards**
*John M. Anderson*
*Jill Ballenger*
*James R. Beardsly*
*N. Kathryn Bender*
*Julie F. Connelly*
*Robin Dills*
*Stephen Fuller*
*Sandy L. Hack*
*James W. Johnson*
*Chris Jones*
*LeAnne D. Kennedy*
*Julienne K. Kirk*
*Peter G. Koval*
*Thomas A. Martin*
*Jerry R. McKee*
*David S. McSwain*
*Stephen R. Novak*
*Karen Petros*
*Regina Schomberg*
*Kelly C. Verzino*
*Michelle W. Welborn*
*D. Montell Yoder*

**1998 Innovative Practice Award**
*Onslow Memorial Hospital*

**1998 Pharmacy Awareness Award**
*Gaston Memorial Hospital and Halifax Regional Medical Center*

**NCSHP Pharmacist-of-the-Year**
*Ronald H. Small*

**Pharmacist-of-the-Year**
*Josiah R. Whitehead*

*Elmore, from page 17*

privilege I really never thought I would have. It's been an exciting year, with many things going on. I've been fortunate to have great people on the Executive Committee with whom to serve, and wonderful staff with whom to work- work which I can truly say was done for the ultimate benefit of the Association, its members, and our profession.

I want to close with a quote from the Membership Task Force report on One Voice-One Vision for Pharmacy which was presented at our meeting last year: "The success of a single organization (for pharmacy) cannot be measured by its membership size, asset mix, or range of activities, but rather by the health and vitality of the profession of pharmacy...."

Thank you for listening, for attending this meeting, and for allowing me to serve as your President.

# North Carolina Pharmacy Unites

by: Brent Spodek

Pharmacists in North Carolina moved forward by returning to their unified roots at this year's convention in Atlantic Beach.

NCPhA members voted 468 to 9 to merge into one unified organization and NCSHP members voted 144 to 3 to do the same.

The North Carolina Chapter of the American Society of Consultant Pharmacists voted to join the new organization in March, and in May the North Carolina Retail Pharmacists Association voted to do the same.

The new organization — the North Carolina Association of Pharmacists, or NCAP — will allow the state's pharmacists to speak with a stronger voice, said Executive Director Dan Garrett.

"This will let us come together with one voice to better educate the public about pharmacy," said Garrett. "It's a profession that uses the knowledge of medicine to help people maintain good health."

The roots of the merger can be traced back to 1994, when Joe Edwards served as president of NCPhA and Dan Garrett was the president of NCSHP.

"Every pharmacist thought they were independent, but they didn't see what we could do together," said Edwards, a past president of NCPhA. "People were not willing or not able to come together for the future of pharmacy."

Garrett and Edwards worked to form the Pharmacy Practice Advancement Committee, which eventually became the North Carolina Center for Pharmaceutical Care.

The move to unify picked up steam in 1997, when a committee chaired by Bill Campbell, dean of the UNC School of Pharmacy, submitted the topic of merger to the Leadership Forum, which is organized by the Board of Pharmacy.

"We couldn't continue to exist as a profession if we were going to go in different directions," said Campbell.

In many ways, merger is a return to roots for pharmacists in North Carolina. The state's first pharmacy organization, the Pharmaceutical Association of North Carolina, was founded in 1880, and until World War II, it was the only professional organization for pharmacists in the state.

But as health care got more complicated, so did the state's pharmacy organizations. In 1947, the U.S. Congress passed the Hill-Burton Act, which funded community hospitals across the country, in an effort to care for returning veterans and to build the health care infrastructure, which had been neglected during the war.

As these hospitals grew, their drug storerooms matured into hospital pharmacies, which needed a more specialized pharmacist - a hospital pharmacist - to manage them.

"At first, there was a generic organization for all pharmacists based on the idea that a pharmacist was a pharmacist was a pharmacist," said Campbell. "The thought was that you could move from one practice setting to another with no additional training and at the time, that was essentially true."

But as the technology got more sophisticated, pharmacists got more specialized. In 1942, the American Society of Hospital Pharmacists split off from the American Pharmaceutical Association, and the split was replicated in North Carolina soon after.

"There was a schism throughout the profession and it was impossible for pharmacists to come together for the benefit of all of us," said Claude Paoloni, former director of UNC's Pharmacy AHEC program. "There were some sectors of pharmacy that thought, "Hell, let the other guys paddle their own boat."

The American Society of Consultant Pharmacists was formed in 1969, with a NC chapter taking root soon after and in the late 1980s, NCRPhA was formed, as more specialties sought the legitimacy and the power that comes from organizing.

"In a lot of ways, we didn't have many options to merger," said Fred Eckel, executive secretary of the North Carolina Center for Pharmaceutical Care. "We weren't making much progress in moving the profession forward. A number of other states had some success with merger, so we began wondering if something similar would work here."

According to many pharmacists who were involved in the merger discussions throughout the 1990s, it was the hiring of Dan Garrett as executive director that made the merger of four separate groups into NCAP a reality. Garrett has served as director of NCPhA and then NCAP since June of 1998, and while he has worked hard for the future of the organization, Garrett says the credit belongs to people like Edwards, Campbell and Eckel.

"The way we got to this point is that Joey Edwards and a lot of the other board members had a vision of where we needed to go," Garrett said. "The driving committee that met in 1998 really gave us the strength to move forward with the unification."

The Driving Committee consisted of the leadership of the four pharmacy organizations — Kevin Almond, Keith Elmore, Mike James, Tim White, Margaret Sgritta, Mike List, Steve Novak and Bill Harris. With the four organizations having come together, many members are hopeful that even more will be done to ensure the future of pharmacy in North Carolina.

"I think it's long overdue," said Frank Burton, who co-chaired the legal and regulatory task force that responded to the unification proposal. "There was a time when pharmacy was much more segmented than it is now, but there are some very compelling reasons for us to come together now. We need more political clout, membership has been dwindling in all four organizations, and we need to face the fiscal realties of operating two or three separate entities."

But while there were practical motivations for merging, the real impetus was the membership's vision for the future.

"We're the most trusted profession, and with good reason," said Edwards. "Now, if we all are saying the same thing, we have instant credibility across North Carolina, from Murphy to Manteo."◎

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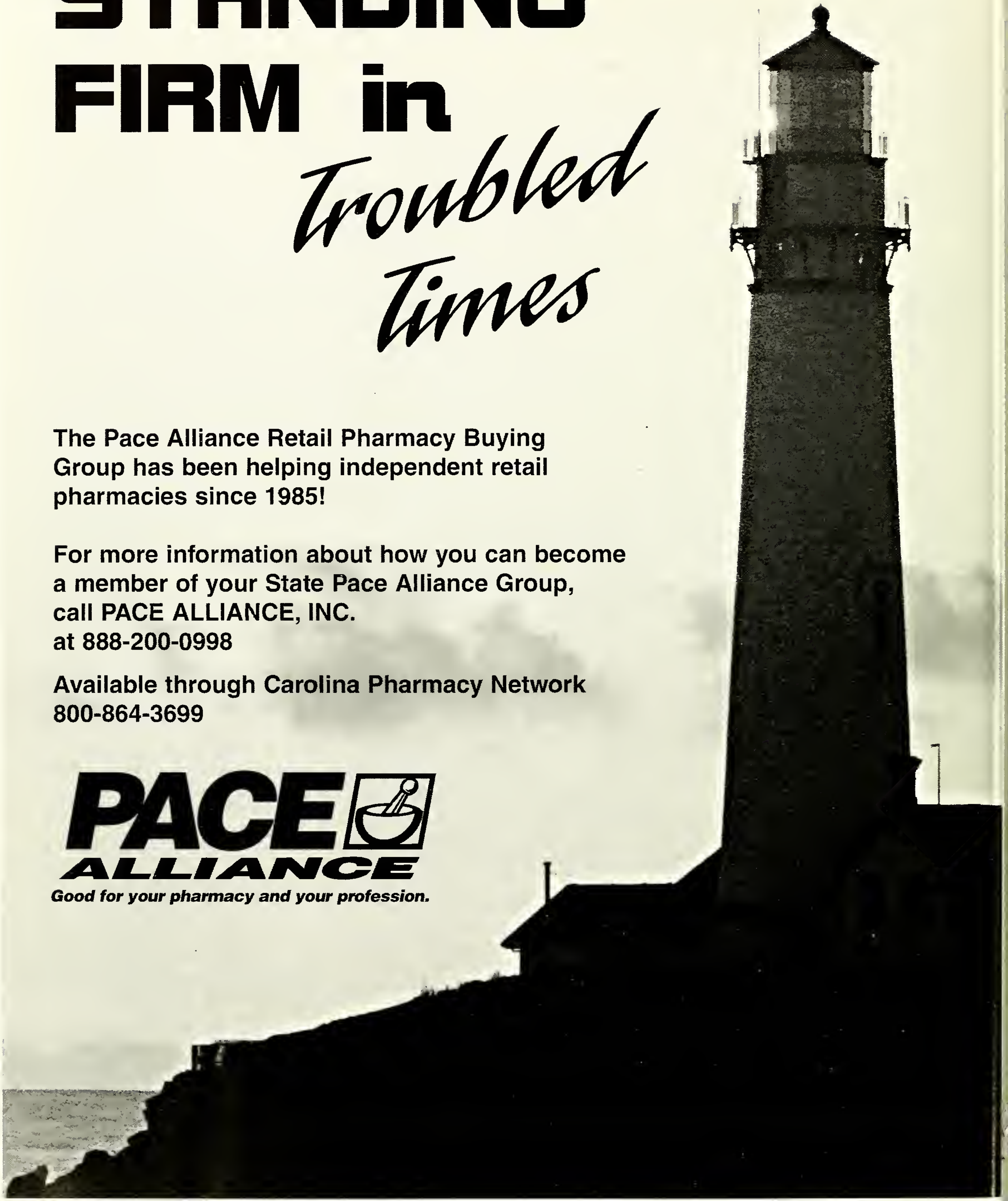

NORTH CAROLINA SOCIETY OF HEALTH-SYSTEM
NCSHP
PHARMACISTS

# Newsletter

Volume 22, Number 4 — The bimonthly publication of the North Carolina Society of Health-System Pharmacists

## From the President

# Medication Safety: What is Our Role?

A common goal of all pharmacists, regardless of practice type, is optimizing the use of medications. Medication errors and adverse drug reactions have become regular topics in the media and professional publications. Pharmacists risk criticism and potential litigation unless we make medication safety a key issue in our minds each day as we fulfill our professional obligations.

NCSHP President
William L. Harris, Jr

The medication use system includes purchasing, inventory, prescribing, preparation, labeling, dispensing, counseling, administering and monitoring patient outcomes. Quality control systems, policy and procedure processes, professional education, practitioner licensure, laws and regulations exist to ensure patient safety. When these systems fail, the patient is at risk for injury, adverse drug effects and/or therapy failure. Experience indicates that there may not be a fail-safe system, but the majority of injuries and deaths from medications are preventable.

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A recent article in the New York Times emphasized the risks of medication use, possibly leading to "death by prescription," as the article was subtitled. The huge increase in medications, prescriptions and therapies has overwhelmed practitioners, and there are predictions that the number of the prescriptions may double in the next five years. All processes and systems are subject to breakdown. Our mission must be to reduce the opportunity for the medication safety systems to fail.

A study published in the April 15, 1998, issue of JAMA estimated that 2.2 million hospital patients were injured and 106,000 patients died in 1994 from adverse drug reactions related to prescription drugs, not including medication errors. The FDA recently issued a request for pharmacists, physicians, hospitals and drug companies to work together to reduce the risks of adverse effects from approved drugs. Manufacturers of drugs with increased risks are now required to distribute explicit warning pamplets to patients.

Actions which pharmacists can take to reduce medication errors and adverse drug reactions include the following:

(1) Use the available technology to help detect potential adverse drug events. Apparently, many computer warnings about drug-drug interactions, duplicate therapy, contraindicated medications, etc., are not used to intervene in the therapy, or the system has been disabled by the user. Pharmacists often cite workload as a reason to override these warnings; we must change our practice to be sure that this information is useful and then take appropriate actions.

(2) Lack of information by the practitioner is often cited as a cause: lack of drug information, lack of information about the prescribed therapy, and lack of patient information. We must improve our resources, communication systems and practices to make the necessary information available.

(3) Patient counseling is crucial for the patients to understand their medications and to take responsibility for their role in successful therapy. We must maintain a current profile of all medications and diagnoses in order to evaluate the overall treatment plan; call physicians when necessary to intervene on behalf of the patient, to make recommendations, and to avoid inappropriate drug therapy.

(4) Streamline the medication use process to eliminate any unnecessary steps. Technology is now available for physician order entry in hospitals and prescription generation for outpatients, but implementation has been slow. Point of care and machine readable code technology provides for electronic safety checks at the bedside for correct patient, drug, time, etc., just before medication is administered and also creates an electronic MAR and billing records. Robotics can reduce the number of steps in handling the medication.

*see Med Safety on page 24*

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NCSHP members are encouraged to share their views, concerns and ideas with their colleagues by contributing articles to the NCSHP Newsletter. Opinions expressed are those of the author and may not represent the views of NCSHP, its officers, Board of Directors or its membership. Copy deadlines are the 10th of the month prior to the month of the next issue to be published. (i.e. April 10th for the May/June Issue.)

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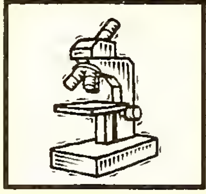
# *Clinical Consultants Corner*



## PHARMACODYNAMICS IN A PHARMACY CULTURE MONITORING SERVICE

by: Craig D. Money

For a number of years, the culture monitoring service at High Point has been concerned with the most cost-effective antibiotic for the organism based on positive culture reports. In the past five years we have progressed to pharmacokinetic drug dosing, monitoring serum levels in comparison to surrogate markers for clinical improvement and avoidance of toxicity. This approach fails to take into account the required blood levels of the drugs for the treated organism. Pharmacodynamics, which describes the relationship between drug serum concentration and the pharmacologic effects of the drug, may be useful in designing regimens that minimize the likelihood of exposing pathogens to sublethal drug levels. This article will review some of the important principles of antibiotic pharmacodynamics and discuss the integration of pharmacodynamic dosing into our Culture Monitoring Service.

### Background

Several questions about antibiotic dosing have always concerned practitioners. Empirically, pharmacists routinely recommend dosing reductions for renal insufficiency. How do we know we are giving enough drug for the organism being treated? A 25-year-old trauma patient is in the ICU; does the *B*-lactam antibiotic need to be dosed every four hours or every six hours? What is the effect of adding another drug to the patient's antibiotic regimen? The patient is a candidate for IV to oral switch — which oral dose is most appropriate for the organism being treated? Should the quinolone dose be every eight hours, every 12 hours or every 24 hours?

Many factors can contribute to the failure of antibiotic therapy; one factor is suboptimal antibiotic concentrations. For patients to be cured of their infections several factors must come together: drug dose, antibiotic clearance based on creatinine clearance, drug concentration at the site of infection, and the minimal inhibitory concentration (MIC) of the bacteria to be treated. When all these factors are right, the patient will be cured of an infection. When bacteria are repeatedly exposed to suboptimal antibiotic concentrations, those bacteria are at risk for developing resistance. Repeated suboptimal drug dosing leads to selection of only the most resistant organisms. Every day we hear about "superbugs" that have become resistance to all antibiotics. We are responsible for this problem by overutilization and under dosing. Research suggests that these "superbugs" are nothing more than "Survival of the Fittest."

Pharmacokinetics and pharmacodynamics are interrelated. The pharmacokinetic properties of a drug characterize the rise and fall of drug concentrations in serum or tissue over time. Pharmacodynamic parameters integrate the microbiological activity and pharmacokinetics of an anti-infective drug by focusing on its biological effects, in particular growth inhibition and killing of pathogens.

On the basis of pharmacodynamic properties, antimicrobial agents can be divided into two major groups. The first group, which includes the fluoroquinolones and the aminoglycosides, consists of agents that exhibit concentration-dependent killing of pathogens. For this group, the higher the drug concentration, the faster the eradication of pathogens. In the second group, which includes the B-lactam antibiotics, peak concentrations are relatively

***see Monitoring on page 24***

# TRANSITION TO AMBULATORY CARE:
# The Lumberton Experience

by: Dana Blecke
& Susan Brown

As healthcare directs its focus to the outpatient setting and chronic disease state management, inpatient pharmacists are often encouraged to consider expansion into ambulatory care. Although this can be an exciting opportunity, it also may present real challenges for staff with a significant acute care orientation.

At Southeastern Regional Medical Center, a 276-bed acute care facility, ambulatory care pharmacy services include patient consultation and education at a multidisciplinary diabetes clinic, as well as a pharmacist-managed outpatient anticoagulation service. Pharmacist protocols for pain and bowel management in hospice care are in place, and a medication indigent care program is being expanded.

We have experienced a number of problems in our transition to inpatient pharmacy practice. The biggest barrier has been staffing management. This includes coverage for the ambulatory care practice while maintaining appropriate inpatient pharmacist support, selection of the pharmacists to provide ambulatory services, and insuring continuity of care between pharmacists. Until recently, ambulatory clinical pharmacy services were primarily provided by a faculty member from the school of pharmacy. On her resignation we were uncertain how those services should be maintained. In defining our staffing plan, we struggled to determine if it is more efficient to utilize inpatient pharmacists to provide outpatient services, or if one pharmacist should continue to be responsible? This question remains unanswered at our institution. For now we have taken a service approach to ambulatory care, with inpatient pharmacists rotating assignments in the various ambulatory care services.

With the current shortage of pharmacists within our community, coverage of the ambulatory care services while maintaining adequate inpatient pharmacist staffing has been extremely difficult. Although our Administration has been willing to allocate additional pharmacist positions to support ambulatory care, positions needed to adequately provide coverage for both the inpatient and outpatient services remain unfilled. In order to balance clinical workload, inpatient pharmacy clinical services have been trimmed, focusing primarily on target diseases or drug therapies. The director and assistant director are covering weekend shifts to allow for the scheduling of more pharmacists for weekday coverage. Outpatient services have also been limited, the number of patients seen restricted, and consideration of service expansion has been slowed. An important question continues to plague our staff: where should our pharmacist resources be placed, and where will our pharmacists have the greatest clinical and financial impact?

Determining which acute care pharmacists would provide clinic services has also been difficult.

Do the competencies in providing acute care translate directly to the ambulatory care setting, or should additional requirements be placed on pharmacists when they move to outpatient practice? As there is less direct physician involvement in the outpatient environment due to the use of collaborative protocols, it was decided that the practice competency requirements should be higher. Pharmacists must complete a diabetes certificate program before they can provide consultation or drug management services in our Diabetes Center. Pharmacists practicing in the anticoagulation clinic are required to complete and pass the department's outpatient anticoagulation competency program. The requirements to participate in collaborative practice agreements in the ambulatory care setting will probably become more comprehensive with the development of Board of Pharmacy rules regulating clinical pharmacist practitioners.

The third challenge we faced was providing continuity of care between pharmacists to ensure appropriate communication of patient-related issues. With multiple pharmacists practicing within each clinic, communication related to patient care is critical. Since a patient may be managed by several different pharmacists over his treatment, full and consistent documentation is required. Efficient time management related to scheduling, consultation time, and documentation procedures is vital to maintaining a proficient service. This coordination of services took much more time than originally planned and is a continuing issue.

A balanced service approach using inpatient pharmacists is our current strategy for providing ambulatory care services. This certainly has some disadvantages both from the patient's and staffs' perspective. But it does enable the department to meet clinical pharmacy needs which may go unanswered, and it does position inpatient pharmacists to improve their practice skills and experience in an increasingly important part of pharmaceutical care delivery.

## About the Authors

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## Call for ASHP Delegate Candidates

If you are an ASHP member and are interested in being a candidate for election as a North Carolina delegate to ASHP for the years 2000 - 2002, please contact Steve Novak, Chair, NCSHP Nominations and Awards Committee, by September 1, 1999. There is one vacancy for the three-year delegate term. Steve can be reached at (704) 834-2239 or novaks@gmh.org.

### *Med Safety, from page 21*

(5) Provide education about adverse drug events to all practitioners and involve all practitioners in reporting medication errors and adverse drug reactions without the fear of blame and punishment . Use the Institute of Safe Medication Practices (ISMP) materials and guidelines, such as writing "units" instead of "u", using a zero before decimals, but not after a decimal, eliminating abbreviations of drug names, avoiding look-alike labels, etc.

(6) Double-check systems should be utilized in the medication use system. A risk of using automated dispensing machines is providing access to medications which can be administered to the patient before the order is reviewed and verified by the pharmacist.

(7) Utilize pharmacy technicians to reduce the workload and provide more time for pharmacists to review drug therapies, verify doses for high-risk medications and in high-risk age groups, participate in clinical rounds, provide pharmacotherapy services and counsel patients.

(8) Utilize specialized computer software to screen orders for appropriate dosage, especially in high-risk medications. Computers can perform dose range checks, screen lab results and generate alerts, warn pharmacists of potential adverse effects and inappropriate therapies, but we must take the time to input or link the patient specific parameters (age, weight, height, lab results, etc.) in order to utilize these features.

(9) Improve the work environment for those pharmacists who report that they do not have the necessary time for breaks, food and bathroom visits. Stress and work volume are often cited as causes for mistakes and overlooking information that could have prevented adverse events.

You may have your own list of medication use improvements for your practice site and patient population. An important step is to make medication safety a goal in your practice and to use all resources available to provide the best possible pharmaceutical care. Our patients expect our best efforts, and we should provide no less.◎

### *Monitoring, from page 22*

unimportant. Instead, the length of time that concentrations are maintained above the pathogen's minimal inhibitory concentration (MIC) is critical to bacterial eradication. Members of this group are referred to as concentration-independent or time-dependent drugs.

#### Incorporation of Area Under the Inhibitory Curve (A.U.I.C.) into the Culture Monitoring Program at High Point Regional Health System

Jerome J. Schentag, Pharm.D., conducted corporate sponsored initial software training during June 1998 for the clinical coordinator with the A.U.I.C. software program. This was followed in July 1998 by a noon conference for the medical staff presented by Dr. Schentag. A core group of the medical staff was interested in evaluating the utility of the program in the care of their patients. Our department began to use the program to evaluate selected patients in the intensive care unit. This process soon progressed from evaluating empiric dosing to include evaluation of antibiotic dosing in patients with positive culture data. The AUIC software program allows those hospitals that do not have specific MIC data to use editable default MIC data. The program also allows individual MIC modification in situations where an organism may be intermediate based on N.C.C.L.S. standards. Initially our hospital reported sensitive, intermediate and resistant (S,I and R) sensitivity data which was changed as of May 1999 to include MIC data. A.U.I.C. software training of the entire pharmacy staff began in September 1998 and is ongoing as new staff are trained. We are currently evaluating outcome data for empiric use versus utilization of the program to evaluate dosing based on specific culture data and MIC's.◎

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*Orlistat, from page 11*

Orlistat were re-randomized to receive placebo, Orlistat 60 mg, or Orlistat 120 mg TID for an additional year. At the end of the first year, a 2.95 kg difference in weight reduction was found between the orlistat and placebo-treated patients ($p<0.001$). At the end of the second year, significantly fewer patients continuing on Orlistat 120 mg TID regained weight, as compared to Orlistat 60 mg TID or placebo ($p<0.001$). Additionally, Orlistat 120 mg TID was associated with a reduction in LDL cholesterol and insulin concentrations. The authors concluded that the addition of Orlistat to dietary modification appears to be useful in producing and maintaining weight reduction.[3]

In a multi-center, randomized, double-blind study, 322 obese patients with type 2 diabetes received either placebo or Orlistat 120 mg TID in conjunction with a reduced calorie diet.[2] The primary purpose of this study was to evaluate the effects of Orlistat on weight loss, glycemic control, and lipid status. Following a placebo lead-in phase, patients were stratified according to weight loss and blood glucose control and randomized to receive either placebo or Orlistat for 52 weeks. At the end of the study period, Orlistat-treated patients lost 6.2 ± 0.5% of initial body weight as compared to 4.3 ± 0.5% in the placebo-treated patients. Additionally, mean fasting plasma glucose decreased in the Orlistat-treated patients (-0.02 ± 0.14 mmol/L) while increasing in the placebo-treated patients (+0.54 ± 0.15 mmol/L). Hemoglobin $A_{1c}$ responded similarly, decreasing in the Orlistat group (-0.28 ± 0.09%) while increasing in the placebo group (+0.18 ± 0.11%). Mean sulfonylurea doses decreased by 23% and 9% in the Orlistat and placebo groups, respectively. Over the study period, orlistat-treated patients showed improvement in total cholesterol, LDL cholesterol, LDL to HDL ratio, triglycerides, and apolipoprotein B. These differences in weight loss, glycemic control and serum lipids reached statistical significance. The authors concluded that patients with type 2 diabetes benefit from Orlistat therapy by reducing weight while improving both glycemic control and lipid parameters.[2]

In placebo-controlled clinical trials, the most common adverse effects from Orlistat are gastrointestinal in nature. Adverse effects reported in at least 5% of patients and occurring at least twice as frequently as in the placebo group included oily spotting, flatus with discharge, fecal urgency, fatty or oily stool, oily evacuation, increased defecation, and fecal incontinence. Gastrointestinal adverse effects may increase as fat intake increases; therefore patients should adhere to a diet containing less than 30% of calories from fat. Adverse effects are generally transient, but may continue for 6 months or more. Other adverse effects include back pain, menstrual irregularity, anxiety, influenza, and upper respiratory tract infection.[7]

Drug interactions have not been detected with digoxin, glyburide, nifedipine, oral contraceptives, phenytoin, or alcohol. The absorption of fat-soluble vitamins (eg, beta-carotene, vitamin E), however, may be reduced. It is recommended that patients take a supplemental multivitamin daily at least 2 hours before or after an Orlistat dose. Although no direct interaction has been demonstrated between Orlistat and Warfarin, altered absorption of vitamin K may affect coagulation parameters. Additionally, concomitant administration of Orlistat and Pravastatin has been shown to result in a 30% increase in pravastatin concentration and additive lipid reducing effects.[7]

Obesity is a common and challenging problem. Continuing research and the advent of new therapies for weight management improve alternatives for patients and clinicians alike. Orlistat offers an alternative to managing obesity with a mechanism of action that differs from other currently available medications approved for weight management. Clinical trials comparing Orlistat to placebo in otherwise healthy[3,6] and patients with type 2 diabetes[2] have produced positive outcomes on weight, lipid profiles,[3,6] and markers of glycemic control.[2] Although gastrointestinal side effects were not uncommon, these effects are generally mild and transient.[7] Orlistat appears to offer both clinicians and patients a novel pharmacologic approach to the management of obesity.

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## *Campbell, from page 8*

Second is the role of the faculty, who in the Middle Ages received no salary but were allowed the use of classrooms by the Chancellor/Dean. Each faculty was free to charge his students whatever he wished. He (and it was always a "he") collected the money, paid for supplies, and was free to keep whatever was left. When the teacher decided his students had "mastered" their education, the University... the Dean... was required to award the degree. Sometimes the dean chose not to award a degree to a certain student, causing conflict between the students who had paid their money and the instructor who had collected fees. So the faculty were always present at graduation to make sure the dean didn't try to withhold a degree, or award one that wasn't authorized by the faculty. So that is the historical reason for the faculty's presence, to make sure I do exactly what they told me to do.

Thirdly, the role of the graduates. The true description of what we do is not to "award" or "confer" a degree, but to admit a student to a degree. The term degree is more like the meaning of a degree of temperature or a degree on a compass, it is one step in a long series of steps. The graduates are here to be admitted one step forward, with the expectation they will continue advancing a degree at a time. Historically, when graduates were admitted to degrees, they were introduced by their mentor, who gave a lengthy introduction, then each graduate gave a lengthy speech to those in attendance, thus proving their worthiness. Then everyone debated the meaning of these presentations in a series of debates (disputations) that lasted 40 days. This ceremony was called the "inception," or the beginning of one's career. We've shortened all that from 40 days to about one hour.

Fourthly, the last role is that played by the audience, representing the public. A fundamental requirement of an inception ceremony was that it be seen and heard by valid witnesses. You are here to note the words of the dean/chancellor, to note the gowns denoting various degrees and credentials of the faculty, to observe that the faculty and dean don't have a conflict over who does or does not receive a degree, and to attest to the worthiness of the graduates.

Why do we do all this? Why keep alive an ancient ceremony? Some people have no use for ceremonies and regard them as vanities. But for most of us there is a real point to celebrating the major events of our lives. A bar mitzvah, a 21st birthday, a wedding, a baptism, all emphasize the fact that one event is a memorable occasion. Today's occasion commemorates that our graduates have taken an important step in being admitted to a degree. It is a matter of joy and achievement, and I congratulate you. But though it is the end of a grueling day, it is not an end, it is an INCEPTION, an admittance to a degree.

In the ceremony we are about to perform, your teachers declare their faith in you. I acknowledge the legitimacy of that declaration of faith and admit you to a degree. You will mount the steps of this platform so that we all see you in the robes of the University of North Carolina at Chapel Hill. At the end, we will have admitted you as one of ourselves. When you leave this hall, you will carry the honor of this university, and our faith in you, on your shoulders.

So we all have important, indeed essential, roles to play in the ceremony about to take place. I invite you to enjoy the occasion in whatever role you play in the timeless pageant of graduation.

## *Asthma, from page 15*

summary bibliography is available upon request from the authors. Significant short-term improvements include reduced beta-agonist use, increased inhaled corticosteroid use, increased peak flow meter use and understanding, improved metered dose inhaler technique, increased compliance with medications, improved clinical parameters (less wheezing, nocturnal cough, and better exercise tolerance), and reduced OTC drugs used for asthma. In regards to long-term outcomes, pharmacists have been able to show reduced emergency department visits, reduced number of hospital admissions, reduced drug costs and overall medical resource costs, fewer missed school days. Additionally, several humanistic outcomes are significantly improved by pharmacists' interventions such as improved knowledge of asthma care, increased satisfaction with care, improved perception of the quality of care, and increased confidence in asthma care. Overall, pharmacists have been shown to have an important role in affecting short and long-term outcomes in asthma patients. Based on our experiences and on a variety of state and national meetings with other healthcare practitioners, notable problems are consistently present among asthma patients: 1) lack of prescribing of anti-inflammatory drugs in persistent asthma, 2) inability of patients to use inhalers properly, and 3) medication noncompliance. Pharmacists can have an impact on all three of these very important problems in asthma.

The final message that we want to relay is that you consider participating in an Asthma Certificate Training Program, even if you do not want to ultimately become a CAE. Minimally, it can elevate the practice of participating pharmacists in assisting in optimizing drug therapy of asthmatics. There are several of these certificate programs that are available in N.C. and nationally. As mentioned earlier, the Asthma Board supports quality asthma certificate programs. ASHP and APHA have or are developing certificate training programs for pharmacists. The American Lung Association has an Asthma Certificate Training Program available on computer. The NARTC is currently offering their program in the U.S. this year that involves a workbook and mentor-student learning. On a local level, there will be an Asthma Certificate Training Program at UNC School of Pharmacy in late July and another Asthma/COPD Certificate Training Program at the Friday Center (UNC-Chapel Hill) in late October. Most of these programs are sponsored or co-sponsored by an ACPE approved provider so that those who participate are eligible for CE credit in all states.

There are some very real opportunities for pharmacists in asthma. We need to be at the forefront in our communities in doing our part in managing these patients. We need to be at the forefront on a national level to ensure that we can be a defined part of the CAE process. If pharmacists do not collectively get involved now, there is a good chance we will lose opportunities to be part of the healthcare team that is paid to help these patients. There is so much we can do to help asthma patients in many of our work settings. We can make an impact on an asthmatic's life!

### About the Authors:

*Roy A. Pleasants, PharmD, BCPS works at Duke University Health Systems and can be reached at pleas005@mc.duke.edu. Philip T. Rodgers, PharmD, BCPS works at the UNC School of Pharmacy.*

*McAllister, from page 8*

creation of a referral network, similar to those used by physicians. If we focused on helping patients get well and provide continuing expert oversight, we would engender patient loyalty and gain tremendous respect (and all that goes with both).

This "new" behavior may cause us to think differently about our role or motive in providing medications to patients, in its physical sense, to more effectively managing drug therapy regardless of the business consequences. It may take the form of challenging physicians to rethink the pharmacotherapeutic decisions they have made, or to more thoroughly educate patients about their drug therapy and not leave it up to mass media advertising to do our jobs. Zellmer concludes his article by offering 10 suggestions for nourishing the soul of pharmacy. I would like to describe five of particular relevance to this graduating class.

1. Encourage ambulatory patients to select a personal pharmacist. Not a pharmacy, but a pharmacist. This notion resonates with the pharmacist referral network concept;
2. Teach pharmacists how to recognize and resist corporate edicts, both blatant and subtle, that undermine their ability to care for patients. In other words, the patient always comes first;
3. Recognize and honor pharmacists who have demonstrated an authentic professional commitment to patients. We need more heroes in the frontline ranks of pharmacy. The position I hold often brings me praise for organizational success, and I must strive to push these caregivers that work for me into the limelight;
4. Increase efforts to develop and enrich the work of frontline pharmacists in all practice settings. We must not become distracted from the fact that the true nature of our discipline is defined in the everyday interface between pharmacists and patients; and
5. Foster a nationwide dialogue among pharmacists, physicians, and consumer representatives about the problems related to medication use and what these three groups can do together to make the situation better. Your families and friends can help us move this idea forward.◎

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# Letters to the Editor

## BCBS Changes Hurt Edenton Pharmacist

To the Editor:

In the midst of Blue Cross/Blue Shield of North Carolina's latest edict to pharmacists serving their subscribers, Beth Williams of NCAP presented a program to the Northeastern (Carolina) Pharmacists Society on June 16, 1999. She asked the members of the group what they thought was the most memorable line from the movie "Jerry McGuire." Most thought it was "Show me the money," but she countered that perhaps it was the line spoken by the elderly gentleman who was being squeezed (recognize that word?) out of the company by the younger Tom Cruise: "It's all about relationships."

I have thought about that line a great deal in the days since. I am a pharmacist owner who for the past 30 years has been the custodian of a century-old practice. Among other flaws, I have two that I will admit to here: I like to stay busy and I give a damn about my patients, especially my long-term ones, those who have been here for two, three generations or more.

When our "friends" in the "glass house" first implemented the "Advantage" (whose?) program, I did not "participate." I continued to file claims for my patients but eventually succumbed to the pressure of the "EOBs" showing billed/allowable differentials. As we all know, the reimbursements have gone from bad to worse, with the latest "offerings" off the scale. In addition, many of our patients still expect and many need our services of store accounts and delivery.

We've all seen individual prescriptions where we could actually "make more money if a competitor filled it," but NCBCBS seems intent on extending this logic (or lack of same) to an entire group of insured that we in fact are already subsidizing on a true cost basis.

As I interacted last week with a delightful, long-term NCBCBS patient, she spoke with my pharmacy-student daughter (UNC 2002) who was assisting me and inquired about my son, a resident physician in Charlotte and said she hoped they might someday serve the community in the family tradition. Thus, to put it "Blountly," it tears my heart out to think of severing relationships (at least on a participating basis) with patients such as this. But there was a story about sand and lines, or was it David and Goliath.

J.G. "Jim" Blount, Sr., BS RPh. UNC'66

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## NC has a Strong Presence at ASHP Meeting

To the Editor:

Reno, Nevada hosted the ASHP Annual Meeting, June 6-9, 1999. As usual, North Carolina was well represented, and our delegates took an active role in the House of Delegates. Former NCSHP President and outgoing ASHP President Bruce Canaday reported on ASHP activities this year to the membership in a general session. This new element was a nice change as Bruce shared how the Leadership Agenda guided ASHP activities. ASHP membership has increased slightly, although the average age of the membership increased, suggesting that new graduates are not joining the Organization to the same degree as before. Meeting the needs of new graduates seems to be an opportunity for all pharmacy organizations.

The ASHP may have had too many meetings in Nevada, because the overall attendance was down this year. Even if Reno is not an ideal meeting city, as I heard many people suggest, the educational sessions I attended were excellent. The issues of corporate compliance and patent confidentiality were covered well and alerted the attendees to potential problem areas.

The business casual approach to the meeting provided a relaxed feel that everyone seemed to enjoy. The many favorable comments suggest that ASHP will continue this approach in the future.

Fred Eckel, Executive Secretary, NCSHP

The Carolina Journal of Pharmacy welcomes letters from NCAP members and others. Letters should be limited to 250 words and may be edited for clarity or length. Please address all letters and other correspondence to:

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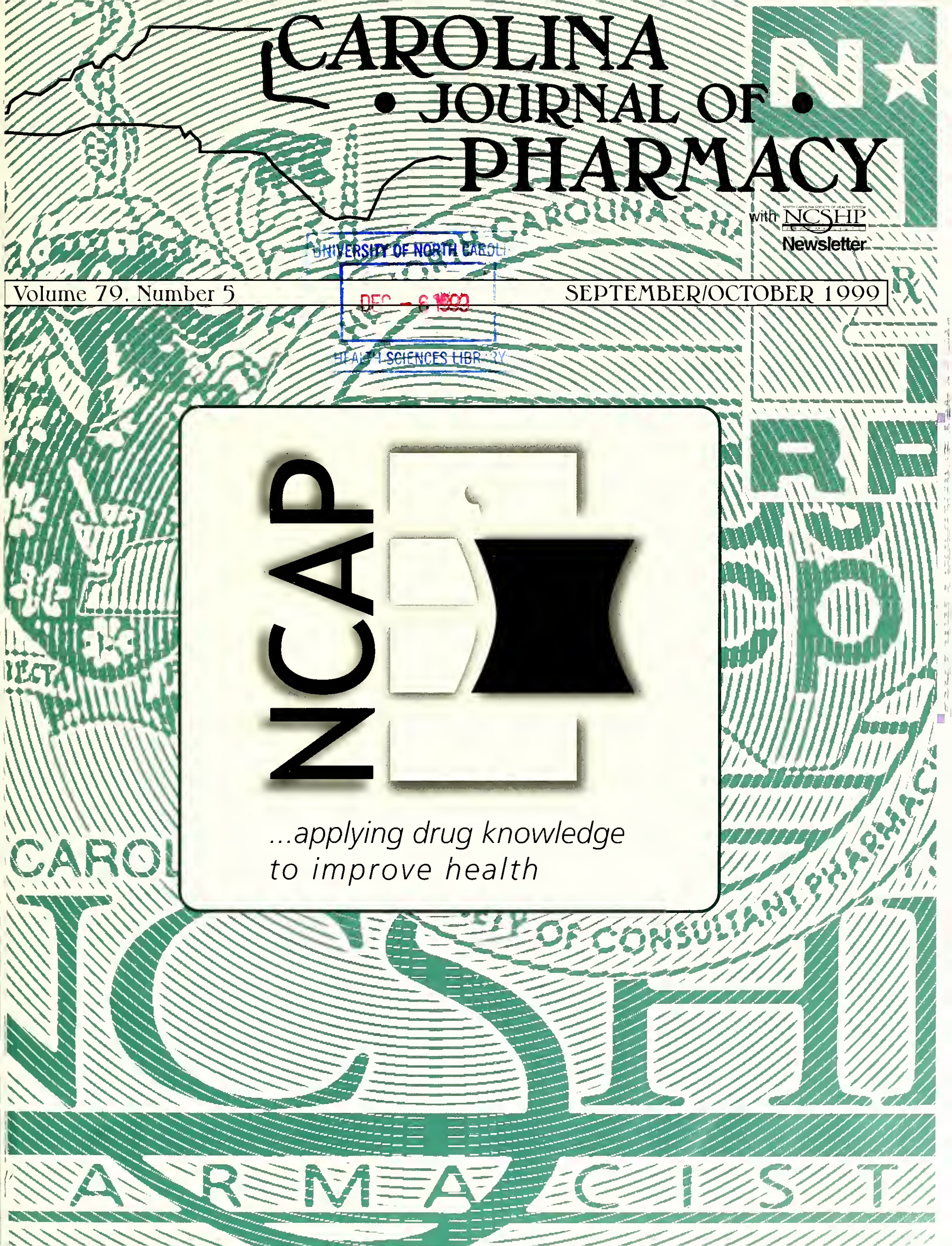

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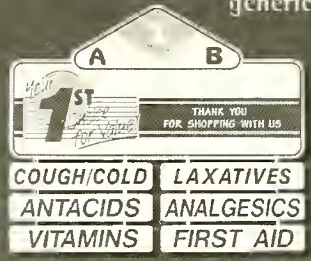

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Daniel G. Garrett
Executive Director

# BEING PHARMACISTS BY GIVING CARE

*Imagine an elderly man coming into your practice, concerned that his arthritis medication might react poorly with his diabetes regimen. He doesn't care about your years of schooling or your encyclopedic knowledge of pharmacokinetics. None of that is relevant to him or his wallet unless pharmacists can marshal our expertise to help this man.*

Recently, while I was in Hickory to make a presentation to the Catawba Valley Society of Pharmacists, I fell into a conversation with Lewis Ferguson, a community pharmacist from Taylorsville.

Many pharmacists are proud of their education and think they should get paid for what they know, he said. But Lewis said he also knew the public isn't interested in paying us for what we know – nor should they be. They are interested in what we can do to help them.

Imagine an elderly man coming into your practice, concerned that his arthritis medication might react poorly with his diabetes regimen. And more than that, he is concerned about the state of his body in his later years. He doesn't care about your years of schooling or your encyclopedic knowledge of pharmacokinetics. None of that is relevant to him or his wallet unless pharmacists can marshal our expertise to help this man.

But the North Carolina Association of Pharmacists is taking steps to make sure that we can help him. One of the most important projects we are involved in is the replication of the Asheville Project. With support from GlaxoWellcome, Inc. through the North Carolina Center for Pharmaceutical Care, we are helping 15 communities from around the state replicate this innovative undertaking, which puts North Carolina pharmacists at the forefront of fighting chronic diseases such as diabetes and asthma.

This isn't wishful thinking or speculation. This is a real development that is taking place in the North Carolina pharmacy community, and that's good because in recent years there has been a lot of talk among North Carolina's pharmacists — talk about clinical practice, talk about standing up to dictatorial HMOs, talk about paperwork problems.

But at the end of the day, it was just talk.

Divided and unfocused, we never were able to move ahead on issues of great importance. But now, unified under a strong and growing NCAP, pharmacy in North Carolina is making great strides forward with programs like the Asheville Project's replication.

In recent months, we have seen:

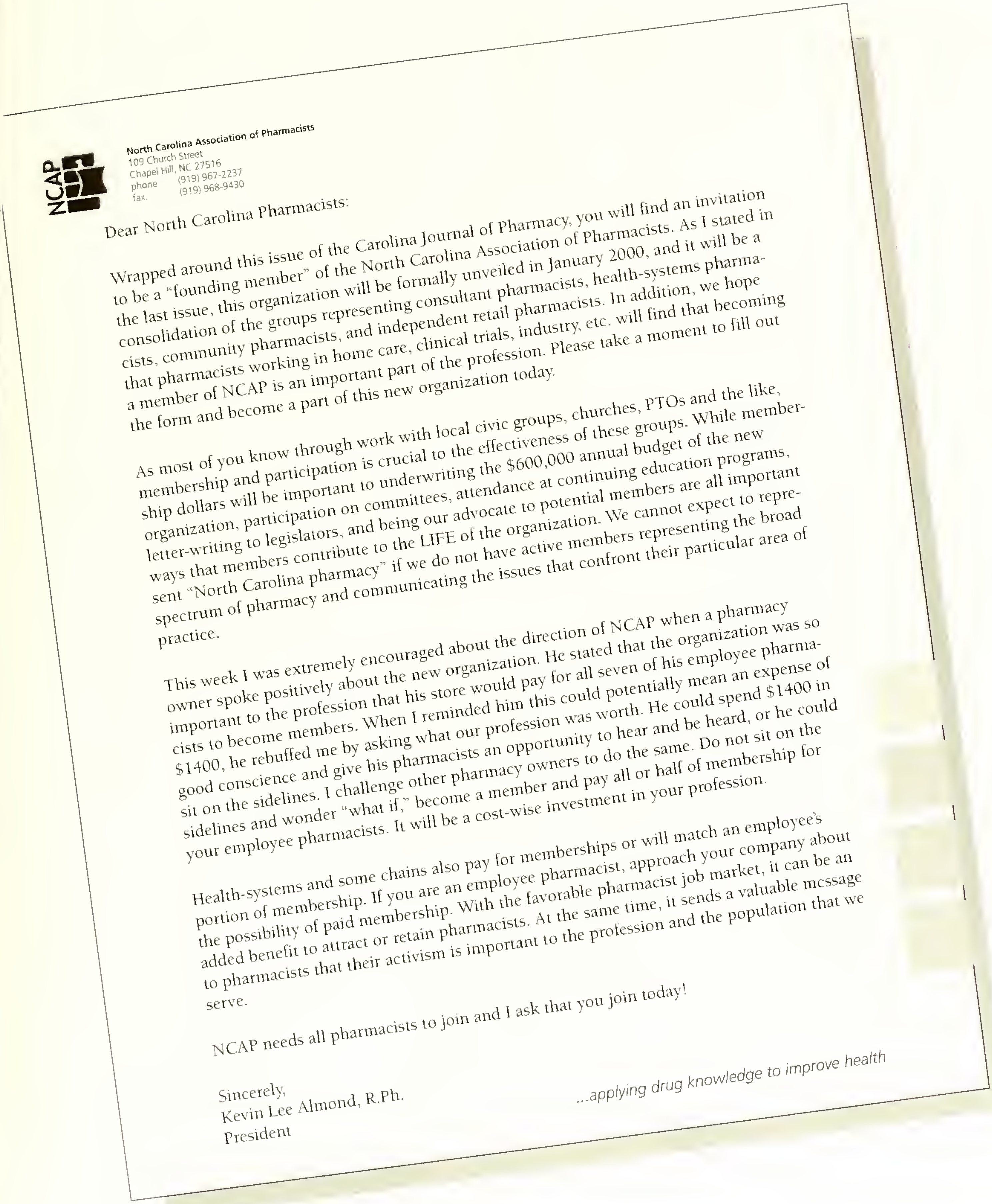
- The General Assembly pass a Clinical Pharmacist Practitioner Act that will allow us to work with physicians more closely than ever before
- The GA also passed a Universal Prescription Card Act that will lighten the load on pharmacists who are overwhelmed by the bureaucratic demands of HMOs
- Pharmacists refuse to sign a BlueCross BlueShield Contract that doesn't even cover the costs of filling their prescriptions
- Forward-thinking pharmacists in Greensboro come together to form an independent provider network that will encourage the use and reimbursement of pharmacists for clinical services.

But now is not the time to lose our momentum. Now is not the time to think that there are others who will carry on the fight for us.

Wrapped around the cover of this issue of the *Carolina Journal of Pharmacy* is an invitation for you to become a founding member of the new North Carolina Association of Pharmacists – the organization that is helping pharmacists apply drug knowledge to improve health. I sincerely hope you will tear the cover off and send it back to us with your membership dues *today*.◎

---

*Dan Garrett can be reached at dan@ncpharmacists.org or (800) 852-7343.*



**North Carolina Association of Pharmacists**
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Dear North Carolina Pharmacists:

Wrapped around this issue of the Carolina Journal of Pharmacy, you will find an invitation to be a "founding member" of the North Carolina Association of Pharmacists. As I stated in the last issue, this organization will be formally unveiled in January 2000, and it will be a consolidation of the groups representing consultant pharmacists, health-systems pharmacists, community pharmacists, and independent retail pharmacists. In addition, we hope that pharmacists working in home care, clinical trials, industry, etc. will find that becoming a member of NCAP is an important part of the profession. Please take a moment to fill out the form and become a part of this new organization today.

As most of you know through work with local civic groups, churches, PTOs and the like, membership and participation is crucial to the effectiveness of these groups. While membership dollars will be important to underwriting the $600,000 annual budget of the new organization, participation on committees, attendance at continuing education programs, letter-writing to legislators, and being our advocate to potential members are all important ways that members contribute to the LIFE of the organization. We cannot expect to represent "North Carolina pharmacy" if we do not have active members representing the broad spectrum of pharmacy and communicating the issues that confront their particular area of practice.

This week I was extremely encouraged about the direction of NCAP when a pharmacy owner spoke positively about the new organization. He stated that the organization was so important to the profession that his store would pay for all seven of his employee pharmacists to become members. When I reminded him this could potentially mean an expense of $1400, he rebuffed me by asking what our profession was worth. He could spend $1400 in good conscience and give his pharmacists an opportunity to hear and be heard, or he could sit on the sidelines. I challenge other pharmacy owners to do the same. Do not sit on the sidelines and wonder "what if," become a member and pay all or half of membership for your employee pharmacists. It will be a cost-wise investment in your profession.

Health-systems and some chains also pay for memberships or will match an employee's portion of membership. If you are an employee pharmacist, approach your company about the possibility of paid membership. With the favorable pharmacist job market, it can be an added benefit to attract or retain pharmacists. At the same time, it sends a valuable message to pharmacists that their activism is important to the profession and the population that we serve.

NCAP needs all pharmacists to join and I ask that you join today!

Sincerely,
Kevin Lee Almond, R.Ph.
President

*...applying drug knowledge to improve health*

# NC PHARMACY - READY FOR Y2K

## It'll be "Business as Usual" on Jan. 1, 2000, say North Carolina's Pharmacists

Chapel Hill – North Carolina's pharmacists say there is no reason to be concerned about difficulty in getting prescription drugs in the new year.

"Because of the diligent efforts of pharmacists, pharmaceutical manufacturers and distributors, we are well equipped to provide the public with the drugs they need in the new year and beyond," said Dan Garrett, R.Ph., executive director of the North Carolina Association of Pharmacists.

"We recommend that customers refill prescriptions normally, or when they have a five to seven-day supply of medication remaining. This is recommended practice not only for January 1, 2000, but for all other times as well. The supply system is extremely resilient and can respond to any issue that might arise within five to seven days," said Garrett after meeting with pharmacy and health care leaders from across the state on Sept. 22.

Not just in North Carolina, but around the country, pharmacists are gearing up to help Americans with any health problems they might encounter.

"Our membership is known throughout the nation for putting the interests of our patients first… the country's independent community pharmacists are taking the necessary steps to ensure quality service to their patients as we transition into the next millennium and beyond," said Calvin J. Anthony, Executive Vice President of the National Community Pharmacists Association.

### The Pharmaceutical Supply System is on Schedule for Y2K

- Manufacturers, wholesalers, retailers, and health care professionals have been working closely together to prepare for the Year 2000 date change.
- As a whole, the industry has been involved in a wide range of key initiatives to assess our readiness, including a thorough examination of the supply distribution system.
- We are confident that the supply system will continue to function normally through the January 1, 2000 transition.
- We do not anticipate any abnormal problems in meeting the demands for prescription medicines.

### Y2K Means a Commitment to Doing "Business as Usual" for the Pharmaceutical Supply System

- The pharmaceutical industry is taking the Y2K transition seriously.
- Contingency plans have been enhanced in anticipation of any unexpected Y2K issues.
- As a result, when Year 2000 arrives, we anticipate that our pharmacy will conduct "business as usual."
- Pharmacists will continue to fill customers' orders in a normal fashion.

### Y2K Means "Business as Usual" for the Consumer

- Consumers should continue to refill prescription medications when they have a five to seven-day supply remaining.
- Y2K is an excellent opportunity to review with patients that this is good practice for January 1, 2000 and for all other times of the year.
- The supply system is resilient and can correct issues that might arise within five to seven days.
- Consumer over-buying can lead to a shortage of supplies, posing a greater impact on the distribution system than Y2K itself.
- Pharmacists should encourage customers to be responsible in their preparedness and refill prescriptions five to seven days before running out.

### The Pharmaceutical Supply System Has a History of Meeting Patients' Needs In Emergency Situations

- The pharmaceutical supply system is often called upon to deliver prescription medicines to areas devastated by hurricanes, tornadoes and other natural disasters.
- Based on this experience, the industry developed a rapid response network to deliver pharmaceuticals wherever needed.
- The rapid response network has been reviewed and enhanced in anticipation of Y2K.
- We are confident this rapid response system will meet patient demands should system disruptions occur.

# NCAP WOULD LIKE TO WELCOME OUR NEWEST MEMBERS:

Laura C. Allen of Wilmington
Jane P. Archer of Morehead City
Kathryn K. Badorrek of Clemmons
Gregory S. Barham of Reidsville
Richard J. Becker of New Bern
Kitty Mae Benfield of Salisbury
Michelle B. Bozovich of Greensboro
Phillip E. Bozovich of Greensboro
Leighton C. Burks of Charlotte
Ernie L. Cline of Hickory
Delbert M. Cranford of Denton
Otis W. Creech of Raleigh
Michelle E. Crow of Greensboro
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Melissa A. Durkee of Raleigh
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Kristen Fanning of Chapel Hill
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Camille P. Robinette of Salisbury
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David Rumberg of Beckly, WV
Melissa M. Rumple of Angier
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Elizabeth S. Skirvin of Glen Ellyn, IL
William F. Stewart of San Francisco, CA
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William K. Tapscott of Burlington
Brandon L. Taylor of Tahlequah, OK
Sarah E. VanBoskerck of Winston-Salem
Paul M. Walker of Newton
Courtney D. Weller of Raleigh
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November 19, 1999

---

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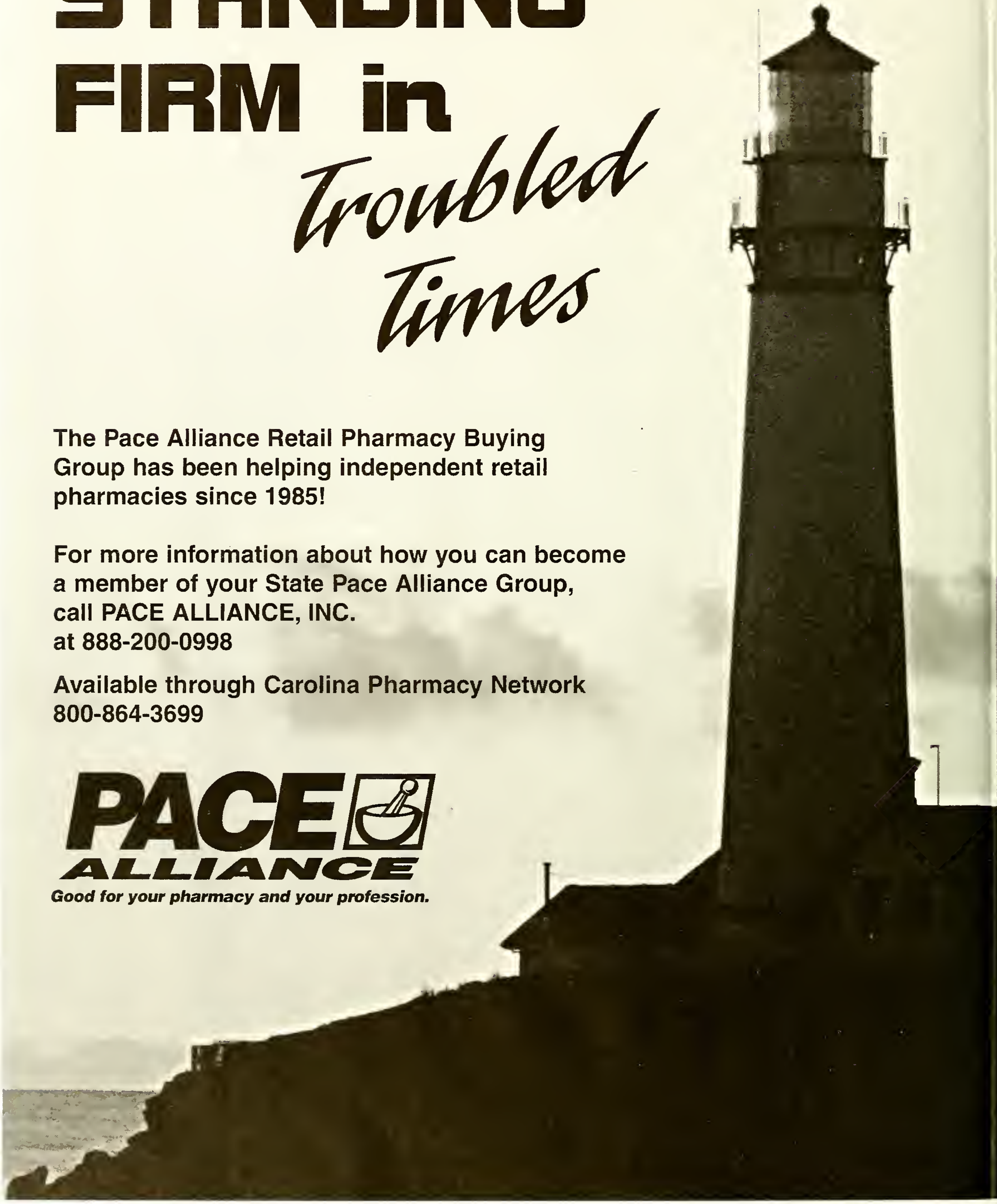

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# TABS THAT CAN BE HALVED

## Cutting Pills to Cut Costs

by: Julienne K. Kirk

The cost of medication is an on-going issue for pharmaceutical and patient care. Some tablets available by prescription can be split in half and potentially decrease overall medication expenditure. For certain populations, such as pediatric patients and older individuals, it may even be necessary to use half or partial tablets to provide smaller dosages of a medication than those supplied by the manufacturer. Many oral tablet prescription preparations can be divided without extensively altering the pharmacologic properties. In some situations, however, tablets are not intended by their manufacturers to be broken in half because of their size, thickness, or design. In addition, certain states do not allow the dispensing of split tablets.

Tablets that are elongated and deeply scored on both sides are usually the easiest to split in half. The tablet should also be large enough to permit a firm grip on each end.[1] It is important to consider drugs that have a wide therapeutic window, where the risk for drug toxicity is not an issue. The pharmacist may be concerned about the accuracy of tablet splitting and the exact amount of pharmacologically active drug that is obtained as variability in the tablet weight once it is split in half can occur.[2,3] Therefore, it is very important to consider the possible risk of therapeutic failure and drug toxicity versus the benefit when selecting tablets to be halved.

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For medications that can be divided, an inexpensive "tablet splitter" (usually less than $10) made of rigid plastic in a box with a partition in which a tablet can be placed may be offered to the patient for splitting. A steel blade affixed to the lid cuts the tablet when the device is closed.[1] While a tablet splitter may be a good alternative for some patients, one study found that tablet splitters did not improve the accuracy of dividing tablets into two equal parts.[2] If a tablet splitter is going to be used, patients should be instructed about the proper placement of the tablet to avoid cutting themselves when placing or removing a tablet. In addition, rough tablet edges may occur with very large formulations once the tablet is split, and patients should be queried about any swallowing difficulties. Tablets that shatter or do not consistently break in half when division is attempted are probably not ideal for splitting. Furthermore, extended-release tablets, such as glipizide (*Glucotrol XL*), as well as those that contain a wax or matrix coating are not candidates for tablet splitting.

There are some examples of tablets that can safely be split in half and lead to cost savings. Examples of antidepressant drugs include the 100mg dose of sertraline (*Zoloft*) that can be used in some patients at a dosage of 50mg once daily or the 30 mg dose of mirtazapine (*Remeron*) may be dosed at 15mg in some individuals. Valacyclovir (*Valtrex*) 1gram tablets, used for the suppression of genital herpes, can easily be split in half to accommodate the recommended daily dose of 500mg. The 100 mg dose of fluvoxamine (*Luvox*), used to treat obsessive-compulsive disorder, can be initiated at a dosage of 50mg (half a tablet) daily, but most patients will need a higher dose for maintenance therapy. These are only a few examples in the author's experience.

For many patients the cost savings can be significant for tablets that can be split. Given the ongoing search for drug cost-effectiveness, tablet splitting may be an option for some medications. Choosing the appropriate drug and patient ease with the tablet splitting process must be considered. ◎

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### About the Author:

*Dr. Julienne Kirk is an Assistant Professor in the Department of Family and Community Medicine at the Wake Forest University School of Medicine, Winston-Salem, N.C. She can be reached at jkirk@wfubmc.edu via e-mail*

# The Juiciest Pharmacy Meeting of the Year!

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# DOPA – MORE THAN A DOPAMINE PRECURSOR

by: Elizabeth McGuffey

What is DOPA anyway, if not a precursor to a well-known neurotransmitter? To pharmacists in North Carolina's Research Triangle area, DOPA is the Durham-Orange Pharmacists' Association. It was previously called a "pharmaceutical" association, but since our membership is comprised of pharmacists (i.e., real people) and not drug products, we realized that a "pharmacist" association was a more accurate description. This change is consistent with the state-wide effort to consolidate community, hospital, industry, and consultant pharmacists into one "pharmacist" organization, the North Carolina Association of Pharmacists (NCAP).

> The pharmacists in local pharmacy associations gain a tremendous advantage with their NCAP affilation because of NCAP's recent successful effort to unite various pharmacy organizations in North Carolina under one umbrella. Uniting pharmacists and increasing membership into a single organization will combine resources and provide a more representative voice for our profession in addressing serious issues that confront pharmacy today.
>
> A single state pharmacy organization will allow better communication of ideas and concerns. Local associations can more easily voice their opinions to one central organization, and that organization can more effectively keep its membership informed of financial and political developments. Pharmacists need unification, organization, and cooperation if we are to preserve our profession.
>
> *Lewis Holder, President,*
> *Catawba Valley Society of Pharmacists*

DOPA meets on a monthly basis from September to May, with no meetings scheduled during the summer. For the past several years, we have been convening at the Willowhaven Country Club for a social hour followed by dinner and a CE presentation. Members start arriving at 6:00 p.m., dinner is served at 7:00 p.m., and we usually adjourn by 8:30 p.m. Having already spent eight or more hours at work plus two more hours at DOPA, most members are eager to get home as soon as possible.

The basic format of socializing, eating, earning CE credit, and getting home early has been in place for a long time and seems to meet the needs and wants of local pharmacists. In most cases, a pharmaceutical manufacturer sponsors each meeting by providing food, drink, and a CE program. When a sponsor cannot be found, the cost of a buffet dinner is $22.00. One hour of contact CE credit is awarded.

Attendance at DOPA meetings consistently averages 75, which sounds good until you consider that there are more than 650 pharmacists in Durham and Orange Counties. High attendance is undoubtedly limited by the long hours of pharmacy operation in most practice sites, precluding 100% participation by pharmacists.

DOPA functions solely on the volunteer efforts of its members, and the only sources of income are dues and grants. Basically, three people are responsible for the operation of DOPA, with the president having the lion's share of responsibility. (S)he takes care of securing a meeting place, food, sponsor, and program, distributing CE credits, and serving as a spokesperson for pharmacists collectively for whatever need may arise. It's easy to see why there is a high rate of burnout for DOPA presidents. A secretary mails meeting announcements and takes reservations and a treasurer handles

*Continued on page 29*

## NORTH CAROLINA'S LOCAL PHARMACEUTICAL ASSOCIATIONS

**Alamance County, Burlington**
**Blue Ridge, North Wilkesboro**
**Cape Fear, Fayetteville**
**Catawba Valley, Hickory**
**Cleveland County, Shelby**
**Columbus-Bladen, Whiteville**
**Crystal Coast, Morehead City**
**Davidson County, High Point**
**Down East, Kinston**
**Durham-Orange, Durham**
**Four County, Henderson**
**Foothills, Elkin**
**Gaston County, Gastonia**
**Guilford County, Greensboro**
**Harnett County, Dunn**
**Haywood County, Canton**
**High Country, Boone**
**Johnston County, Smithfield**
**Lincoln County, Lincolnton**
**Mecklenburg County, Charlotte**
**Moore County, Pinehurst**
**New Hanover County, Wilmington**
**Northeastern, Williamston**
**Northwest, Winston-Salem**
**Onslow County, Jacksonville**
**Person County, Roxboro**
**Piedmont, Concord**
**Pitt County, Greenville**
**Randolph County, Asheboro**
**Richmond County, Rockingham**
**Sampson-Duplin, Kenansville**
**Southeastern, Lumberton**
**Surry County, Mt. Airy**
**Union County, Monroe**
**Wake County, Raleigh**
**Wayne County, Goldsboro**
**Western Carolina, Asheville**
**Wilson County, Wilson**

# Ground level views of community pharmacy...

With the focus of today's healthcare on ambulatory settings, the community pharmacists can position themselves as innovators in the management of their patients' diseases, such as diabetes. This challenge provides for an exciting career opportunity for me.

**Cathy Allen Teat,**
**Ward Drug Co. of**
**Nashville**

As a supporter of pharmaceutical care, I think it is important for our newest colleagues to have some "hands-on" experience in pharmaceutical care as licensed professionals. In addition, it is an opportunity for them to use their clinical expertise in developing new pharmaceutical care programs and assist in improving current ones.

**Bill Horton,**
**Residency Director**
**PSA Beverly Hills**
**Pharmacy,**
**Asheville**

I feel that health care is not always continuous from intervention to outcome. Patients can fall through the cracks in the system and appropriate follow up is not always done. I feel that community pharmacists have a great opportunity to help bridge this gap. By counseling patients on medications, providing education on disease states and offering recommendations, we can help patients reach desired outcomes.

**Jason S. Southworth,**
**Central Pharmacy,**
**Durham**

# COMMUNITY PHARMACY RESIDENCIES MAKING HEADWAY

by: Wendy Everhart

Most encounters between patients and their healthcare providers occur at community pharmacy counters. More patients see their pharmacists for new prescription services than see their physicians for acute or even chronic healthcare needs. In the community setting, pharmacists have an opportunity to have a significant impact on patients' disease states. But only in recent years have pharmacy school curricula focused on experimental education and training for the "cutting edge community pharmacist," a trend that is augmented by the expanding interest in pharmaceutical care. While those are significant steps, there is a need now for more high quality clinical community residency programs. In the past, residencies have been limited to hospitals and ambulatory care facilities affiliated with hospitals or universities. Pharmacists who wished to pursue careers in a progressive community pharmacy have been left with few options.

In December of 1997, Bennett's Pharmacy in Greensboro became the first pharmacy in North Carolina to host a community pharmacy resident. The store is owned by Michelle and Phillip Bozovich, both 1994 graduates of the UNC School of Pharmacy. The Bozoviches also own Drug Therapy Management, Inc., (DTM) a consulting business designed to promote patient care within their pharmacy and in physicians' offices. Their goal was to establish a clinical community residency to promote disease state management in the pharmacy and in surrounding physicians' offices. Bennett's Pharmacy boasts a private 600-square-foot counseling room for scheduled private consultations.

I became the pharmacy's first full-time resident in July1998. The following is an overview of my residency experience. I hope this information will inspire more progressive community pharmacists to begin their own residency programs and generate interest in this form of post-graduate education among pharmacy students.

My experiences with Drug Therapy Management, Inc. (DTM) began long before my actual residency program. As a fourth-year student in the Pharm.D. program at UNC-Chapel Hill, I spent a one-month clerkship with Michelle Bozovich, Pharm.D. at Western Rockingham Family Medicine. DTM contracted with Western Rockingham Family Medicine to provide in-house clinical pharmacy services three days a

***Continued on page 27***

## The Emergence of Community Pharmacy Residencies

by: Steve Caiola

Two years ago, there were no community-based postgraduate pharmacy residency training programs in North Carolina. Today there are five. Hospital/health-system residency training has over a 30-year history in our state. Only recently has the need for advanced practice training in community pharmacy practice caused some risk-taking practitioners and the state's two Schools of Pharmacy to sponsor such programs.

A few North Carolina community pharmacists are expanding their practices to include pharmaceutical care services to satisfy unmet needs of their patients. These services are producing, or at least may produce, new revenue streams. Extensive compounding services and selected disease state management programs (e.g., the Asheville Project) have been initiated. These services are both professionally satisfying and lucrative. The pharmacists leading the way in providing these services are finding that more experiential education and training are required for practitioners to step in and make a difference in their increasingly sophisticated practice settings. Here is where community pharmacy residencies

***Continued on page 26***

## RESIDENCY PROGRAMS IN NORTH CAROLINA

- Underline indicates the residency is co-sponsored by Campbell University.
- *Italics indicate the residency is co-sponsored by the University of North Carolina.*

**Ambulatory Care**

Mission+St. Joseph's Health System, Asheville

**Community Practice**

*Bennett's Pharmacy, Greensboro*
Central Pharmacy, Durham
*Kerr Drug, Chapel Hill*
PSA Beverly Hills Pharmacy, Asheville
Ward Drug Company, Nashville

**Drug Information**

Campbell University, Buies Creek
*Glaxo Wellcome, Research Triangle Park*
Wake Forest University Baptist Medical Center, Winston-Salem

**Family Medicine**

Department of Family Medicine, affiliated with UNC Hospitals and the UNC School of Pharmacy, Chapel Hill
East Carolina University School of Medicine, Greenville

**Geriatrics**

Alamance Regional Medical Center, Burlington
Methodist Retirement Community, Durham
*VA Medical Center, Durham*

**Pharmacy Practice**

Carolina's Medical Center, Charlotte
Duke University Medical Center, Durham
Gaston Memorial Hospital, Gastonia
Mission+St. Joseph's Health System, Asheville
Moses Cone Memorial Hospital, Greensboro
NorthEast Medical Center, Concord
Southeastern Regional Medical Center, Lumberton
University Medical Center of Eastern Carolina, Greenville
UNC Hospitals, Chapel Hill
VA Medical Center, Durham
Wake Forest University Baptist Medical Center, Winston-Salem

**Primary Care**

Coastal AHEC/New Hanover Regional Medical Center, Wilmington
Kaiser Permanente/Southern Regional AHEC, Cary/Fayetteville
UNC Hospitals, Chapel Hill
*VA Medical Center, Durham*
VA Medical Center, Salisbury
Wilson Community Health Center, Wilson

**Specialty**

Duke University Medical Center, Durham — Internal Medicine/Infectious Diseases/Academia
Moses Cone Memorial Hospital, Greensboro — Anticoagulation Management
*UNC Hospitals, Chapel Hill — Anticoagulation/Oncology/Hematology*
*UNC Hospitals, Chapel Hill — Infectious Diseases*
*UNC Hospitals, Chapel Hill — Pediatrics*
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# MAKING YOUR VOICE HEARD

by: Fred M. Eckel

I hope my perspective is wrong, but my recent observations suggest that too many pharmacists feel that they are not in control of their own professional future. I am not sure this can be explained by the increasing number of employee-pharmacists. It is true that often an individual employee feels powerless against the "company." Afraid to stand up for what they believe is right, because they could be fired, they look for solutions from others. Calls from pharmacists for Boards of Pharmacy to take actions to insure good working conditions suggest that the individual pharmacists feel powerless, themselves, and need someone else to fight their battles. In some cases, we see individuals joining together to pursue legislative relief of their perceived injustices. Some see unions in our future as the best way to gain control.

When we lose the sense that we are in control of our own professional decisions, both the pharmacist and the patient lose. It is time to reverse this situation and take control of our professional future. A strong North Carolina Association of Pharmacists (NCAP) will be one important step in our re-professionalization. But many are unsure how their voice will be heard in NCAP. There are many ways to have input into decisions in the new organization.

One major change will be the opportunity for local associations to affiliate with NCAP. During the first year, 2000, the leadership of NCAP will focus on forming as many local association affiliates as possible. Just think what pharmacists can accomplish when synergy between the local and the state association is activated.

Another major opportunity for pharmacists to have a voice will be in the House of Delegates, where local associations will send representatives based on their number of members. This House will be "the policy-making body of the North Carolina Association of Pharmacists." This means that the local association members will be able to influence NCAP policy development directly through service as a delegate or indirectly through the local association's delegate. Pharmacy schools and Practice Forums will also have seats in the House. The House of Delegates will become operational in the year 2001.

The other major component of the NCAP that will provide opportunity for making your voice heard is the Practice Forums. A Practice Forum will provide pharmacists with special- interest opportunities to learn together. Initially there will be Practice Forums for chronic care, acute care, ambulatory care, and technicians. Your NCAP membership entitles you to membership in one Practice Forum. Each Practice Forum will be represented on the Board of Directors and on the four Standing Councils, which will be the major policy development group for the NCAP.

Finally, yet another way to provide individual pharmacists with a way to influence NCAP activities is in the election of geographically-based members to the Board of Directors. Since the Board of Directors is the governing body of the NCAP, this means that any member should be able to call their regional representative and express their interest in seeing specific actions taken.

Hopefully, each pharmacist in the NCAP will realize that what they want to see accomplished may not be viewed by others as in the best interest of pharmacy or the organization. The new structure is designed with appropriate checks and balances so that all opinions and ideas can be heard, but only policies or programs that the majority feel are good for pharmacy and the patients we serve will become Association policy. When pharmacists can agree to put the patient and the profession ahead of their special interests, we will have power and influence. A strong NCAP may not meet everyone's expectations all of the time, but the structure should ensure that most pharmacists' expectations will be met in the long run.

Without a majority of pharmacists as members, however, NCAP will struggle financially and be a weak advocate for the profession. The first step in making your voice heard is to join NCAP. Currently, only about 25% of North Carolina pharmacists are members of one of the four statewide organizations. We have to do better than that in order to make our voices heard. Try membership in NCAP. You might find out that you can have an impact on your professional future.◎

About the Author:

*Fred Eckel is the Executive Secretary of NCSHP and can be e-mailed at fred_eckel@unc.edu.*

NCAP

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# THANK

### Constitution & Bylaws Task Force

Developed the NCAP constitution and by-laws, which reflect the unification of the NCPhA, NCSHP, NC-ASCP and NCRPA and facilitate NCAP's ability to maintain an affiliation with each national organization.

*Ginger Lockamy - Chair*
*Steve Novak - Driving Committee Liaison*
*Steve Caiola*
*Vance Collins*
*Walter Davis*
*Fred Eckel*
*Tim Giddens*
*John Kessler*
*Larry Long*
*Mark Ninno*
*John Setzer*
*Wyn Sterling*
*Tom Thutt*
*Marianne White*

### Education Task Force

Developed a strategic plan for providing quality continuing education in a variety of settings, including statewide meetings, local/regional meetings, internet, and mailings.

*Anna Garrett - Chair*
*Don Marsh - Vice Chair*
*Margaret Sgritta - Driving Committee Liaison*
*Jill Ballenger*
*Robert Bizzell*
*Laura Brewer*
*Steve Caiola*
*Bruce Canaday*
*Patricia Cash*
*Vance Collins*
*April Cooper*
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*Deb Smith*
*Mike Soucie*
*Dan Teat*
*Tracy Thomason*
*Keith Tinkham*
*Joyce Tipton*
*Macary Weck*
*Ann Wilkins*
*Tracy Wilson*
*Jane Younts*

### Finance Task Force

Developed a financial plan to allow NCAP to function as an effective and profitable association over the next three years.

*Randy Ball - Chair*
*Keith Elmore - Driving Committee Liaison*
*Vance Collins*
*Steve Dedrick*
*Anna Garrett*
*Bill Harris*
*John Kessler*
*Katie McDonough*
*John Nance*
*Steve Novak*
*Deb Smith*
*Raymond Wong*

### Legal & Regulatory Task Force

Provided input and support of NC pharmacy's 1999 successful legislative initiatives, the Clinical Pharmacist Practitioner Act and Universal Prescription Card Act - a great example of what can be accomplished when pharmacists from different practice settings work together for the overall advancement of the profession!

*Ken Burleson - Chair*
*Frank Burton - Vice Chair*
*Mike James - Driving Committee Liaison*
*Bob Allen*
*Randy Angel*
*Paul Bissette*
*Jim Boyd*
*Ross Brickley*
*Valerie Brooks*
*Wesley Byerly*
*Bob Carta*
*Wayne Creech*
*Betty Dennis*
*Jean Douglas*
*Melissa Durkee*
*Tim Giddens*
*Catherine Gray*
*Colleen Gresham*
*Bill Harris*
*Henry Herring*
*Jimmy Jackson*
*Joe Johnson*
*Pete Koval*
*Tim Kurek*
*Vince Lee*
*Phil Mendys*
*Brenden O'Hara*

**NCAP would like to extend a big "thank you" to all of the committee members who have worked so hard to make unification happen.**

# YOU!!

*Jim Pierce*
*Bill Post*
*Charles Reed*
*Leslie Richard*
*Ron Small*
*Billy Smith*
*Gray Stewart*
*Monte Thompson*
*Davie Waggett*
*Ken Wallace*
*Jack Watts*
*Macary Weck*
*Michelle Welborn*
*David Wheeler*
*Tim White*
*Ellen Williams*
*Dennis Williams*
*Mary Katherine Williams*

## Marketing & Communications Task Force

Developed a marketing campaign to NC pharmacists in order to have a successful unified organization. Planned the NCAP website and other methods of timely and effective communication

*Jennifer Burch - Chair*
*Kevin Almond - Driving Committee Liaison*
*Tim White - Driving Committee Liaison*
*Kathryn Bender*
*Jennifer Burgess*
*Steve Caiola*
*Mitch Camp*
*Terri Cardwell*
*Vance Collins*
*Amanda Corbett*
*Linda Cross*
*Melissa Durkee*
*Stephen Eckel*
*Alyce Holmes*
*Jane Hughes*
*Teresa Jones*
*Ariel Mihic*
*Whit Moose, Jr.*
*Deanna Moretz*
*Mark Ninno*
*Brenden O'Hara*
*Regina Schomberg*
*Tom Smith*
*Brent Spodek*
*Graham Stephens*
*Vince Stevens*
*Kim Thrasher*
*Louis Weaks*

## Membership Task Force

Developed a plan for membership benefits and services to retain 100 percent of the 2,500 members of the current organizations, as well as to attract new members from among the 4,000 non-member NC pharmacists

*Beth Williams - Chair*
*Mike List - Driving Committee Liaison*
*Cindy Bishop*
*Mike Brewer*
*Valerie Brooks*
*Karen Campbell*
*Frank Catoe*
*Debby Collins*
*Steve Critz*
*Kami Dell*
*Melissa Durkee*
*Randy Eckard*
*Kim Edwards*
*Jill Garris*
*Bob Greenwood*
*Bryan Haas*
*Ashley Hoover*
*LeAnne Kennedy*
*Julie Kirk*
*Kevin Layne*
*Gene Minton*
*Kolleen Newsome*
*Brenden O'Hara*
*Teressa Reavis*
*Jodie Ritchie*
*Tom Schendel*
*Regina Schomberg*
*Jane Thompson*
*Julie Tolle*
*Van Weaver*
*Lori Wilson*

## Professional Relations Task Force

Developed a plan to improve relationships with industry and other health care professionals.

*Benny Ridout - Chair*
*Bill Harris - Driving Committee Liaison*
*David Adkins*
*Lynne Alexander*
*Jay Brower*
*Bob Carta*
*Frank Catoe*
*Melissa Durkee*
*Beth Early*
*Jill Garris*
*Tim Giddens*
*Mark Gregory*
*Colleen Gresham*
*Johnny Hogg*
*Joe Johnson*
*Steve Kearney*
*Lynne Kearns*
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*Charles Reed*
*Steve Rogers*
*Lloyd Ruona*
*Steve Russell*
*Ron Small*
*David Smithwick*
*David Spain*
*Ellen Williams*
*Mary Katherine Williams*
*Ron Winstead*
*Mike Wooten*
*Jim Zaleski*

## Transition, Dissolution & Operations Task Force

Developed a plan to allow for the effective merger and governance of NCAP

*Joe Moose - Chair*
*Dan Garrett - Driving Committee Liaison*
*Judy Crouch*
*Fred Eckel*
*Tim Giddens*
*Thadd Hirschy*
*Ralph Hunter*
*Joe Johnson*
*Todd King*
*Jim McAllister*
*Debbie Montague*

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# FDA Unveils New Labels for OTC Drugs

by: Jennifer B. Harris

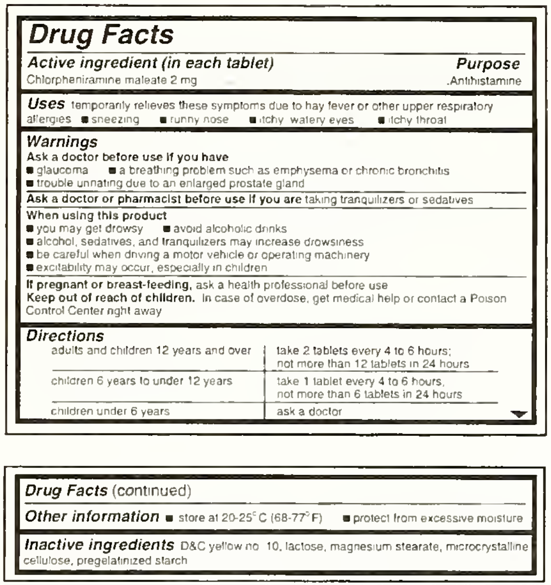
The look of over-the-counter prescription drug labels is changing. On March 11,1999, Vice President Al Gore announced a new FDA regulation that will unify nonprescription product labeling. Under the new regulations, products will be required to use a new label format that includes larger print and clearer language. Also included with this regulation is a national public information campaign to educate consumers about over-the-counter products and their new labels. As stated by Vice President Gore:

> *In this new regulation I am unveiling today, we will ensure that the labels on medicine we buy over-the-counter are no longer written over our heads. Starting here and now, when children wake up sick in the middle of the night, parents won't have to read a dictionary to read the directions. And people won't need a magnifying glass to find out what's in their medicine.*

The need for the new regulation arose out of growing concerns surrounding the misuse of over-the-counter remedies. Currently, Americans purchase five billion over-the-counter products each year. Misuse of these medications results in over 170,000 hospitalizations annually at a cost of $750 million. Studies estimate that improved consumer information and education could prevent half of these hospitalizations. Children and the elderly are especially at risk for nonprescription drug misuse. Unclear dosing instructions can result in accidental underdosing or overdosing of children by their caregivers. Older Americans are at risk because small print sizes can make some labels unreadable.

Specifically, the new FDA regulations require a standardized format that lists ingredients and their uses in the same location on every over-the-counter drug and drug cosmetic. Officially entitled "Drug Facts," the new labels will also include proper dosing instructions and appropriate warnings. The new labels will direct consumers with questions to "ask your doctor or pharmacist," a change from the less specific "health professional" that is commonly used on current labels. Some technical terms such as "indications," "precautions" and "contraindications" will also be eliminated or replaced with easier to understand terms. The regulation specifies a minimum type size of six points, still smaller that the eight point type used in most classified advertisements, but larger than the type used on many current labels. Nonprescription drug packages that are too small for the standardized label will be allowed a modified format. The FDA is also requesting, but not requiring, that manufacturers include a telephone number for consumers to call with questions about the product. The new label should be appearing on drug products within the next two years and will be required of every over-the-counter medication in six years.

In order to educate the public on these new product labels for nonprescription drugs, the FDA will also launch a public information campaign. This campaign will include public service announcements in newspapers, magazines and radio as well as distribution of information through professional organizations such as the National Association of Chain Drug Stores. The information included in this campaign will not only address the new drug labeling but will also invite the public to ask questions of their health care providers concerning their medications. This additional encouragement will allow pharmacists more opportunities to help patients make the best use of their medication.



**Drug Facts**

| **Active ingredient (in each tablet)** | **Purpose** |
|---|---|
| Chlorpheniramine maleate 2 mg | .Antihistamine |

**Uses** temporarily relieves these symptoms due to hay fever or other upper respiratory allergies ■ sneezing ■ runny nose ■ itchy watery eyes ■ itchy throat

**Warnings**

**Ask a doctor before use if you have**
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are** taking tranquilizers or sedatives

**When using this product**
■ you may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

**If pregnant or breast-feeding,** ask a health professional before use
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away

**Directions**

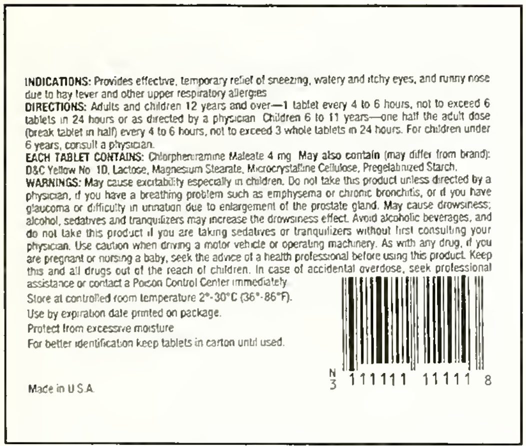
| | |
|---|---|
| adults and children 12 years and over | take 2 tablets every 4 to 6 hours;<br>not more than 12 tablets in 24 hours |
| children 6 years to under 12 years | take 1 tablet every 4 to 6 hours,<br>not more than 6 tablets in 24 hours |
| children under 6 years | ask a doctor |

**Drug Facts** (continued)

**Other information** ■ store at 20-25° C (68-77° F) ■ protect from excessive moisture

**Inactive ingredients** D&C yellow no 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

*The new OTC label, recently introduced by the FDA in an effort to improve readability.*



**INDICATIONS:** Provides effective, temporary relief of sneezing, watery and itchy eyes, and runny nose due to hay fever and other upper respiratory allergies
**DIRECTIONS:** Adults and children 12 years and over—1 tablet every 4 to 6 hours, not to exceed 6 tablets in 24 hours or as directed by a physician Children 6 to 11 years—one half the adult dose (break tablet in half) every 4 to 6 hours, not to exceed 3 whole tablets in 24 hours. For children under 6 years, consult a physician.
**EACH TABLET CONTAINS:** Chlorpheniramine Maleate 4 mg **May also contain** (may differ from brand): D&C Yellow No 10, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch.
**WARNINGS:** May cause excitability especially in children. Do not take this product unless directed by a physician, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland. May cause drowsiness; alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages, and do not take this product if you are taking sedatives or tranquilizers without first consulting your physician. Use caution when driving a motor vehicle or operating machinery. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.
Store at controlled room temperature 2°-30°C (36°-86°F).
Use by expiration date printed on package.
Protect from excessive moisture
For better identification keep tablets in carton until used.

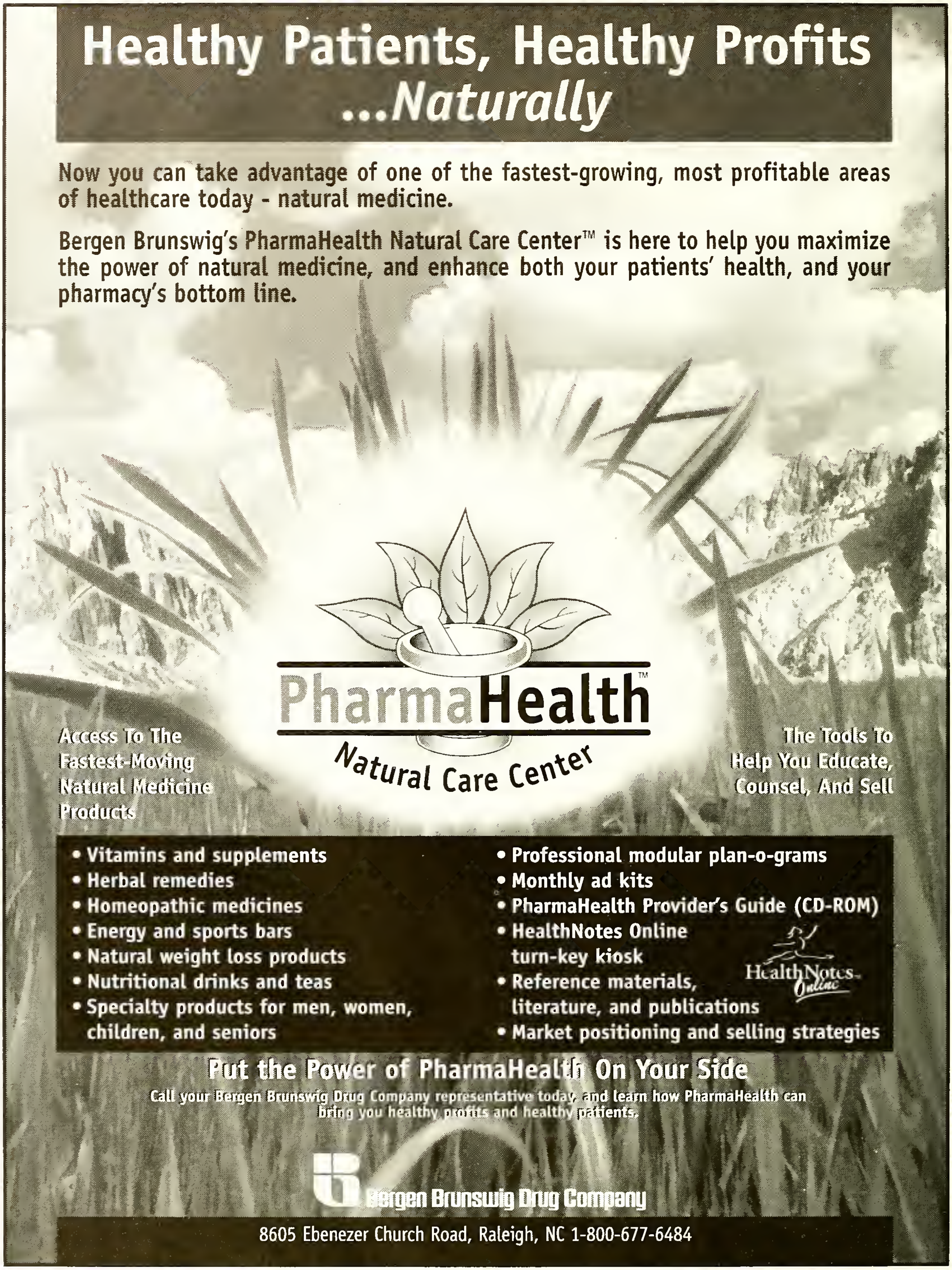
N 3 111111 11111 8

Made in U.S.A.

*The old OTC label, which is being phased out by the FDA.*

## About the Author:

*Jennifer Harris, M.S., is a fourth year pharmacy student at UNC. She can be reached at kerri-epcc@mindspring.com*



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# PRIVATE PHARMACIES FEEL THE PINCH

## New insurance contract will mean prescriptions filled below cost

Three privately owned pharmacies in Wilson aren't going to sign a new contract that would force them to fill prescriptions at below cost for BlueCross BlueShield of North Carolina.

Terminal Drug, Thomas Drug and Wilson Drug stores stand together against the contract, said Sid Harmon of Terminal Drug Store. So are many other independent drug stores across the state.

No official word is out yet on whether the large chains – Eckerd, CVS, Wal-Mart, and Kmart – will sign.

Deadline to sign the contract is July 26.

by: Laura Keeter

"It's an unfair contract to us and the customer," said Bill Rose of Terminal Drug Stores. "They (BlueCross BlueShield) are basically asking us to fill some prescriptions for less than they cost. And we cannot provide some of the services we provide at less than the rate of reimbursement.

Medicap Pharmacy in Wilson is also privately owned, but part of a national chain. Mike Warren, owner and pharmacist of the Wilson Medicap, said the chain hasn't reached a decision yet, but may accept the contract.

"That's been a tough decision for us," Warren said. "It's a very low reimbursement."

Merck-Medco, an outside company, oversees BlueCross BlueShield's pharmacy benefits, said BlueCross BlueShield spokesman Susanne Powell.

Merck-Medco is striving to provide customers with quality drug benefits at an affordable price, she said.

"At BlueCross BlueShield, and across the country, prescription drugs are the single fastest-growing health care expense," Ms. Powell said. "BlueCross BlueShield of North Carolina has seen the cost of prescriptions go up 20 to 30 percent per year in recent years – that's each year."

The "steep increases" directly affect the cost of providing benefits to customers, she said, and drive up the premiums paid by families and employers.

After Sept. 1, affected BlueCross BlueShield customers can still use non-participatory drug stores, but they'll have to file their own claims. And they may not get reimbursed for every cent they paid.

"We won't be a participatory pharmacy," explained Harmon.

He anticipates that after the deadline BlueCross BlueShield will send out lists of participatory pharmacies. But Harmon says it won't be doomsday if customers stay with Terminal Drug.

We're going to try to make it as pleasant as possible," he said. For example, Harmon will fill out the paperwork for his customers.

Customers will still get reimbursed for the amount BlueCross BlueShield says they should have paid for medicine. That amount is the wholesale price minus 15 percent (which is the cost for which some drug stores are able to buy their drugs), plus $1.50.

That means some pharmacies would make $1.50 total profit on filling the average $40 prescription.

"A dollar fifty doesn't cut it," Harmon says. Drug stores have to inventory drugs, buy containers, label containers, keep records, consult with customers, fill the prescriptions and sometimes make deliveries.

That means overhead for most drug stores is about 25 percent, Harmon said.

BlueCross BlueShield's deal offers about 3 percent to 4 percent gross margin.

Harmon hopes enough drug stores won't sign the contract that Merck-Medco will renegotiate. There's also a chance that a bill in the state legislature, known as the pharmacy choice/competition bill, may offer solutions.

Although major chains have refused to sign contracts in the past, Harmon says this is the first contract the independents have organized against.

A letter he received from N.C. Mutual Wholesale Drug Co., a co-op of about 500 privately-owned pharmacies in the state, encourages member pharmacies not to sign the contract.

BlueCross BlueShield, however, is a huge customer for some stores. Some stores could lose half their business if customers leave to buy at participating pharmacies.

But the stores would lose money anyway if they fill prescriptions at a loss, Harmon says.

"Over the years, we have bit the dust and said, 'I don't like this contract, but I don't want to lose the people I'm dealing with,'" Harmon said. "But now they (insurance companies) are getting to the point where they're getting ridiculous."

Harmon estimates about 20 percent to 25 percent of his business is with BlueCross BlueShield.

A few of BlueCross BlueShield's policies won't be affected by the change, but the majority of plans – about 80 percent – will be, he said.

Merck-Medco is striving to keep down the costs of prescription drugs, said Julie Mandell, spokesman for Merck-Medco. "Pharmacies have the option not to participate if they feel the reimbursement rates are not acceptable to them."

Negotiating competitive reimbursement rates for retail pharmacy services is just one strategy for achieving reduced pharmacy costs, Ms. Mandell said.

Merck-Medco also negotiates discounts from pharmaceutical manufacturers and offers a mail-service pharmacy for customers with chronic conditions.

About the Author:

*Laura Keeter is a staff writer for the Wilson Daily News and can be reached at keeter@wilsondaily.com.*

**Reprinted, with permission, from the July 21, 1999 Wilson Daily News.**

## Practice Profile

# MOOSE PROFESSIONAL PHARMACY

Address: 390 Copperfield Blvd., Concord NC 28025
Phone: (704) 784-9613
Fax: (704)789-9366
Manager: Joseph S. Moose, Pharm.D.
Education: Campbell University, Class of 1990
E-mail: moosedrug2@ctc.net

---

**Describe your overall practice:**
Moose Professional Pharmacy is a 650 sq. ft. independently owned pharmacy that opened in 1989 in the lobby of a North East's Internal Medicine Clinic. Together with the Mt. Pleasant pharmacy which opened in 1882 and Midland, which opened in 1999, we are part of a three store, family-owned and operated pharmacy that has been in business for over a century.

Upon his graduation from Campbell University in 1990, Joe Moose replaced his brother Whit Moose, Jr. who served as the original pharmacist/manager of the Concord location. Whit Jr. then moved to manage the original Moose Drug Co. in Mt. Pleasant. Pharmacist Lori Horn and Whit Moose, Sr. now assist Joe in the Concord location.

**What unique services do you provide?**
When the pharmacy was established we set out to be totally patient-oriented. Our goal was to make each patient transaction one that provided more than the patient expected. Just one example of this would be in problem-solving. We take the time to advocate on the patient's behalf with their physicians or their insurance carrier. At first this seemed to bother some physicians, but it did not take them long to discover that we were working in the patients' best interest and soon the physician came to expect it of us. We also are involved in compounding, hospice, diabetes education, asthma education, women's health (hormone replacement therapy) education, natural medicine education and drug information service for community physicians.

**How did you determine the need for this service?**
When we first opened the new pharmacy, we did not have many patients. That gave us time to talk to and take a personal interest in each of the customers we did have. We began that way, and, although we are busier now, we still do it that way. We talked to a lot of patients, physicians, and employees, and we especially listened to patients when we were counseling them — where there is a complaint; there is an opportunity.

**Are you being reimbursed for the services you provide?**
We are getting paid for many of our services. Sometime it takes longer to collect from an insurance company than it does to actually provide the service. Because of this we are trying to work with more classes and larger groups of people than just one-on-one consultations.

*Moose Pharmacy strives to make each patient transaction one that provides more than the patient expected.*

**What lessons have you learned as a result of this experience?**
You are not going to get paid if you don't bill someone! Persistence, Persistence, Persistence! You often have to bill more than once and follow up. We believe in using other people's ideas, methods, forms, etc. and adapting them to our practice.

**What were you stumbling blocks?**
It is discouraging to send bills and not have them paid. The fact that the services we provide are new to patients and insurance companies makes it difficult to explain the value of these services until they have received them. The time it takes to develop marketing material and market these services is difficult to fit into a busy practice. Because these types of services are new, people do not know what you can do or what services you provide. You have to sell yourself then your services and this has been challenging.

**Where are you heading now with your practice?**
We hope to have the ability to refuse the worst paying third-party contracts by increasing our compounding and disease management consultations and taking care of our patients who value our services. We are developing and marketing disease state management/education programs for groups of people and business. Although we have been in business for 108 years we are still heading pretty much in the same direction that we were then - taking care of peoples' problems.◉

NORTH CAROLINA SOCIETY OF HEALTH SYSTEM
NCSHP
PHARMACISTS

Newsletter

Volume 22, Number 5 The bimonthly publication of the North Carolina Society of Health-System Pharmacists September/October 1999

# From the President

## One Voice....One Vision For North Carolina Pharmacy

What is your vision of the future in pharmacy practice? What talents and expertise do you have that you can share with others to accomplish the mission? The profession of pharmacy in North Carolina has taken big steps forward in the last 18 months to unify the talents, visions and voices of pharmacists in all healthcare settings into a new pharmacy organization. The foundation has been created, but now we need your help in making the unified organization representative of the diverse practice areas in pharmacy.

*NCSHP President William L. Harris, Jr.*

The North Carolina Association of Pharmacists (NCAP) was created by pharmacists of NCPhA, NCSHP, NCASCP and NCRPA who believe that a unified voice will strengthen our position in North Carolina healthcare, help others to recognize pharmacists' importance to patients and open new doors for pharmacy practice. I hope that you are a member of at least one of the above organizations, but if not, that you now recognize the need for all pharmacists in North Carolina to support the new organization. The profession faces financial threats from new reimbursement policies, has been left out of draft language for HCFA proposals in patient care and sometimes is not invited to the table when patient care and healthcare proposals are being formulated. We must correct these oversights by improving our image and visibility.

On July 14, 1999, Governor Hunt signed into law a bill that recognizes that a Clinical Pharmacist Practitioner (CPP) may provide disease management therapy in collaboration with a patient's primary physician. This bill was the culmination of several years of political and clinical efforts by pharmacists, physicians and others to inform, educate and convince legislators that this will benefit patients and assist their physicians in providing individualized care to patients through easy access to a knowledgeable caregiver.

Passage of this bill was facilitated by pharmacists in all practice settings working together. This unified voice convinced our legislators that indeed pharmacists can provide enhanced pharmaceutical care through collaboration with physicians in all healthcare settings in our state. This is only one example of what can be accomplished when all pharmacists in North Carolina work together.

Pharmacists exist to serve the healthcare needs of their patients. This was never clearer than when the mission statement for NCAP was being adopted. The statement began "NCAP exists to unite, serve and advance the profession of pharmacy," but an important point seemed to be missing—the patient. The words "for the benefit of society" were added to clarify why pharmacists seek to advance the profession of pharmacy and what brings us satisfaction. We need a strong pharmacy organization to educate, inform and battle when necessary in order to receive the financial rewards that should accompany our clinical efforts.

The NCSHP Board of Directors, the Driving Committee of NCAP and the leadership of all four of the above pharmacy organizations invite you to join the new organization before the end of 1999. How many pharmacists should become a member of NCAP? The Board of Pharmacy indicates that there are some 6,500 pharmacists practicing in North Carolina. Frankly, we need all of you to fulfill the mission of one voice…one vision. Let us begin the year 2000 with you as a partner in NCAP.◎

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NCSHP members are encouraged to share their views, concerns and ideas with their colleagues by contributing articles to the NCSHP Newsletter. Opinions expressed are those of the author and may not represent the views of NCSHP, its officers, Board of Directors or its membership. Copy deadlines are the 10th of the month prior to the month of the next issue to be published. (i.e. April 10th for the May/June Issue.)

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Clinical Consultant's Corner-
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## *Clinical Consultants Corner*

# THE LATEX SENSITIVE PATIENT IN THE OR SETTING

by: John M. Anderson

Latex allergy is an increasingly recognized phenomenon. The first report of an immediate hypersensitivity to latex originated in Germany in 1927. The earliest known cases in the United States were reported in 1988, after several deaths resulting from an allergic reaction to the latex tip of barium enemas.

Natural latex is the milky sap obtained from the *Havea brasiliensis* plant, also known as the rubber tree plant. After exposure to latex, a patient may become sensitive to an antigen (a water-soluble protein) that occurs naturally in latex. Subsequently, latex sensitivity may develop as a result of repeated exposure to the latex antigen. The sensitivity usually initially manifests as localized reactions. With repeated sensitization, systemic reactions can occur. Progression from a cutaneous reaction to a more severe anaphylactic reaction depends on the quantity of the antigen, type of exposure, route of exposure, and individual characteristics of the patient. A patient who has become sensitized must avoid all contact with latex.

Latex sensitivity can manifest as a type I (IgE-mediated) or type IV (cell-mediated) allergic reaction. A type I reaction produces immunoglobulin E antibodies on exposure to the allergen. Type I sensitivity reactions occur rapidly with exposure. Type IV reactions are the most commonly observed. Type IV reactions are delayed; the allergen activates T-lymphocytes and macrophages, thereby causing tissue damage. Symptoms associated with Type IV are generally less severe. Type IV reactions most commonly noted are contact pruritus, erythema, vesicular lesions, contact urticaria, and eczema. Type I reactions most commonly seen are bronchospasm, wheezing, angina, tachycardia, conjunctival edema, rhinorrhea, and nasal pruritus.

Pharmacists should be familiar with risk factors for latex sensitivity. High-risk populations have been identified and include: health care workers who use latex gloves and products (as many as 14% of health care workers may be sensitive to latex), patients with myelomeningocele and/or a history of chronic or recurrent instrumentation of the genitourinary tract (estimates of 20% to 40% sensitivity in this group) and people with occupational exposure to latex containing products. In addition, approximately 6.5% of the general population is estimated to have a latex sensitivity. Pharmacists have an increasing role to recognize the situation and provide for a latex-free patient setting. Screening each patient on admission for identification of latex allergy should be a standard of care. Pharmacists should continue to monitor closely with each order until the patient is discharged.

The recent increase in the prevalence of latex allergy may be attributed to many situations. A primary contributor is the introduction of universal precautions in an effort to prevent the spread of hepatitis B and HIV. A primary compliance with universal precautions has been through use of latex gloves. This has created a growth industry for latex glove production and has resulted in greater exposure of predisposed health care workers and patients to latex products. Another reason for increased latex allergies is that the increased demand for gloves created a change in the manufacturing process, including

*Continued on page 26*

# TO FILL OR NOT TO FILL:

## Pharmacists' Right to Refuse Based on Moral Convictions

by: Leslie Carter

The right to refuse to fill an order or prescription based on moral or ethical conviction has become a relevant issue facing contemporary pharmacists. Today more than ever, pharmacists are faced with the dilemma of filling an order or prescription that conflicts with their own belief system. The Food and Drug Administration's (FDA) recent approval of the "morning after pill" and partial approval of RU-486 has triggered much publicity and put pharmacists in the hot seat. The "morning after pill" regimen is a larger than normal dose of birth control pills used the morning after unprotected intercourse to prevent pregnancy. Preven is the first birth control pill to be specifically packaged for emergency contraception. RU-486, also known as mifepristone, is used to induce abortion within 49 days of conception. While RU-486 is not available in the United States at this time, it is likely to make it to market. Other issues that have caused conflict include euthanasia, nutrition and hydration, lethal injection, and physician-assisted suicide. Each of these subjects is filled with controversy, and discussion of details is beyond the scope of this article. Each pharmacist has to make his or her own decision as to what is right or wrong, moral or ethical. It is obvious that there will not be a consensus. Should pharmacy as a profession be given the right to refuse to provide a particular legal service or product based on individual specific moral or ethical convictions? As a result of the dilemma, some pharmacists have lost their jobs. While dismissal due to refusal to fill is rare, it has been documented.

Both the pharmacist's right to refuse to fill an order or prescription and the patient's right to acquire legal medications need to be protected. In order to establish precedent, different organizations have begun to approve conscience clauses, written policy recommendations pertaining to the standard of pharmacy practice in the area of a pharmacist's right to refuse based on moral or ethical convictions.

In 1998, the American Pharmaceutical Association (APhA) passed a conscience clause which reads, "APhA recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal." Similarly, the American Society of Health-System Pharmacists (ASHP) policy 9802 states, "ASHP recognizes a pharmacist's right to conscientious objection to morally, religiously, or ethically troubling therapies and supports the establishment of systems that protect the patient's right to obtain legally prescribed and medically indicated treatment while reasonably accommodating the pharmacist's right of conscientious objection." Across the country, certain state organizations have developed conscience clauses, including Pennsylvania, New Jersey, Ohio, and California.

North Carolina organizations have not developed specific conscience clauses. This could be due to the protection that North Carolina pharmacists receive from the Board of Pharmacy Rules and Regulations # .1801. This rule states that, "a pharmacist …has the right and responsibility to refuse to fill or refill a prescription order if, in his judgement, it would be harmful to the recipient, is not in the recipient's best interests or if there is a question as to its validity. The pharmacist…shall report such incident to the licensing board having jurisdiction over the prescriber." North Carolina pharmacists can use "not in the patient's best interest" to justify a refusal to dispense.

A significant number of pharmacists and governing bodies agree that pharmacists should have the right to refuse to fill an order or prescription if it compromises their ethical or moral convictions. The dilemma continues to persist, however, on how patients can be assured of their right to obtain legal medications while simultaneously pharmacists are assured protection in their right to refuse.

While APhA's conscience clause states that it "supports the establishment of systems to ensure patient access to legally prescribed therapy…" it is difficult to determine what will be needed to accomplish this task. Is it the pharmacist's duty to provide legal products to patients regardless of moral or ethical dilemmas? If pharmacists refuse, should they or should they not refer the patient to a pharmacist who will provide the sought medication? To protect patients' rights, will pharmacists be required to passively compromise their beliefs? What will happen if an entire hospital pharmacy staff refuses to fill an order? Will the patient be denied perfectly legal services? There is no easy answer.

Each individual pharmacist should decide what does and does not compromise his or her own beliefs. If those decisions would lead to conscientious refusal, discussion with a supervisor is recommended to avoid conflict or disciplinary action in the future. Secondarily, it will allow the supervisor to make arrangements to enable the patient to get the legal product in question.◎

**About the Author:**

*Leslie Carter is a Pharm.D. at Halifax Regional Medical Center. She can be reached at lcarter@halifaxrmc.org.*

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**Continued from page 24**

shorter wash and shelf times that created higher-protein latex gloves. Increased prevalence is also due to increased awareness and reporting over recent years.

In the OR setting, latex exposure may be from direct contact with latex products, by indirect contact (touching a latex product and then touching the patient) by inhalation exposure (glove or latex product powder), and through injection of materials via IV ports. The obvious way to eliminate exposure is to remove all latex products; unfortunately, this is difficult to do. Therefore, minimization of exposure becomes critical. Cases involving latex sensitive patients should be the first scheduled case of the day in the assigned OR suite. This minimizes exposure to inhalation of latex particles. It also allows for careful planning and barrier protection of latex-containing equipment. Equipment known to contain latex that cannot be removed should be wrapped with roller gauze bandages to prevent direct and indirect contact. Only latex-free syringes should be used.

Medications and administration of fluids may create some problems with the latex sensitive patient. A pharmacist should work closely with the OR nurses, CRNAs and anesthesiologists to determine that medications are safe for use. The pharmacist in conjunction with the Anesthesia staff should establish cassettes that contain drugs that are latex-free (either ampules or latex-free stoppers). *Micromedex, Inc.*, provides a list of vials with latex-free and latex-containing stoppers.

Although there have been no reports or other information implicating contamination of medications with latex from a vial with a latex stopper, the use of medications with latex-containing stoppers causes a dilemma. Coring of a stopper by a needle and thereby freeing latex particles has been a concern but again has not been demonstrated. A conservative approach that is often taken is to have pharmacy remove the stopper in a sterile environment and draw the medication into a latex free syringe. If necessary, reconstitution of drugs for use in irrigations should be prepared by pharmacy to eliminate errors by surgical staff. Medications may be mixed or added to IV solutions by using an additive transfer set through the IV spike (pin) port or by injecting medications through the IV piercing spike port once the pull tab cover has been removed. Latex ports on fluids should be covered with tape to prevent its use.

Latex sensitivity is a serious condition with a potentially fatal outcome. Awareness and education are vital in providing a safe latex-free environment for patients. Pharmacists must become involved in sharing, maintaining up-to-date information and taking an active role in ensuring that patients receive proper screening and care.

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fit the need – the UNC-CH Schools of Pharmacy will be working with all of the state's community pharmacy residency programs, working toward establishing accredited programs at each site.

Though we are not the first state to establish these innovative programs, we are well on our way to establishing sound mergers of education and practice to better serve our state's citizens and ensure successful community pharmacy practice well into the future. This report presents a look at the current status of community pharmacy residency education and training in North Carolina. The experiences and motivation of current and former residents promises an exciting future. Those pharmacists interested in learning more about community pharmacy residencies are encouraged to contact Dr. Larry Swanson at the Campbell University School of Pharmacy (910-893-1718) and Mr. Stephen Caiola at the UNC-CH School of Pharmacy (919-966-4557). Those with access to the Internet are encouraged to review the APhA web page (www.aphanet.org) which describes community pharmacy residencies.

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week. This new and exciting aspect of pharmacy, in which pharmacists were able to make immediate interventions in patient care and monitor their outcomes, fascinated me. When I was selected to be a resident with DTM, I was eager for the opportunities that awaited me. My residency was co-sponsored by the UNC-Chapel Hill School of Pharmacy and the Greensboro AHEC.

My residency was designed so that I spent one day a week in the pharmacy and four days a week in physician offices with my preceptor, Michelle Bozovich. I also spent considerable time researching the different disease states that we manage most intensively and participating in student meetings at the Greensboro AHEC. One month into my residency program I began a diabetes pilot program with a local family practice office. I was given 13 patients to manage and follow for six months. The patient contact and experience I gained through this pilot program was invaluable and led to many new opportunities.

Another very enjoyable part of my residency involved research with pharmaceutical companies. DTM was approached by a contracted clinical research organization (CRO) not long after I began my residency. Dr. Bozovich selected me to be the primary site investigator for all drug studies that DTM managed. My first research opportunity was a population study on the resistance of cold sores to common pharmacologic treatments. I have since used the skills I learned from this experience to participate as an investigator in several other large-scale studies.

During the first six months of my residency program, I assisted Dr. Bozovich in establishing a cardiology lipid clinic. My role was to review lipid lab work and make suggestions for initiating or modifying drug therapy. I was also responsible for recommending additional lab work to rule out secondary causes of dyslipidemias. During my learning process I attended several lipid management training programs, including one at Duke University and Berkley Heart Lab. Dr. Bozovich reviewed my patient notes to guide my learning, and ultimately I found this feedback to be the most valuable part of my training.

During the last six months of my residency program, we began providing anticoagulation services for the cardiology group where we were already providing lipid management services. Additionally, Dr. Bozovich and I met with a cardiologist to discuss starting an intensive lipid management clinic that addressed secondary prevention and non-traditional risk factors for dyslipidemia. We received the contract to begin the lipid clinic in February 1999, and I began forming the lipid clinic and selecting a method for tracking outcomes. Through the progressive use of risk modifications (such as lipoprotein (a), homocystenemia, and particle size) we hope to successfully demonstrate long-term decreases in secondary events beyond that seen in landmark lipid-lowering therapy trials.

Currently, I am employed by DTM and am six months into the management of my lipid clinic. I am also on the speakers bureau for multiple drug companies. Thanks to the practice experiences and opportunities I received during my residency training, I have become a confident and successful pharmacist. Pharmacists: please consider beginning your own community pharmacy residency program to provide other new practitioners this same unique experience.◎

## Changes to Continuing Education

**In order to better serve our members, the *Carolina Journal of Pharmacy* will be mailing a special CE Supplement only to members who request it.**

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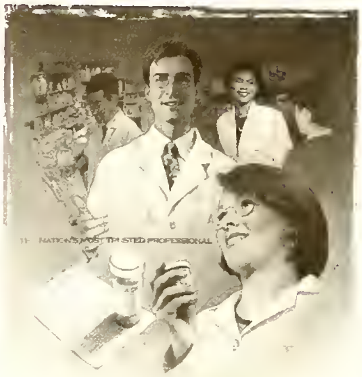
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monies from dues, fees, and contributions.

We all recognize that pharmacists are the most highly respected professionals, according to ten straight years of Gallup polls. This high ranking is due to the activities of pharmacists in their professional capacity and also their active involvement in civic and community life functions. Many DOPA members are active in religious and/or community programs. But collectively, this organization has a very low profile in Durham and Orange Counties. For example, this year the Orange County School Board required that medication to be dispensed during school hours be labeled with the patient's name, physician, drug name, dose, adverse effects, and any drug interactions. Any pharmacist would quickly point out the unfeasibility of this rule. The real question is why wasn't DOPA or a pharmacist consulted before the rule became law?

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The strength of DOPA lies in the diversity of its membership, representing all types of practice sites. But we don't really capitalize on this advantage. As a general rule, there is very little discussion of the program or business in general, this lack of discussion resulting in poor communication among pharmacist specialists. We tend to dwell on our own day-to-day concerns and fail to recognize the concerns of pharmacists in other practice sites. In other words, we fail to have a sound and convincing vision for pharmacy as a whole. As a result, our collective power is weak, and we fail to unite our efforts to promote our common profession. A current DOPA goal is to increase awareness of local pharmacists as a group by enhancing participation in community events.◎

About the Author:

*Liz McGuffey is a pharmacist and professional writer, and a member of DOPA. She can be reached at ecm908@aol.com.*

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# Letter to North Carolina Pharmacists

To North Carolina Pharmacists:

In response to the many questions I have heard recently about the Clinical Pharmacists Practioner Act, I would like to submit the following suggestions for regulations. Please review and discuss these suggestions with physicians you work with and encourage them to contact the Medical Board or the Medical Society with their input.

A Clinical Pharmacist Practitioner (CPP) is a new level of pharmacist care provider which was established by House Bill 1095 and signed by the Governor on July 14, 1999. This bill was developed and supported by the North Carolina Medical Society, North Carolina Academy of Family Physicians, North Carolina Hospital Association and the North Carolina Association of Pharmacists. The bill was a revision of the Medical Practice Act and establishes the "Clinical Pharmacist Practitioner" using language similar to that used for "Nurse Practitioner."

When will this bill be law? The bill becomes law on July 1, 2000. The Medical Board and Board of Pharmacy have until this date to pass regulations to make the bill effective.

What will a CPP do? These pharmacists have advanced training and work collaboratively with licensed physicians to implement predetermined agreements for drug therapy such as aminoglycoside dosing, anticoagulation management, theophylline dosing, pain management, refill programs, and asthma or diabetes care. The CPP regulations will set standards for who can enter into collaborative care agreements and for their implementation and monitoring.

How will a pharmacist become a CPP? Licensed Pharmacists will have to apply to the Medical Board for approval as a CPP. It has been suggested that this process be similar to the one used by Nurse Practitioners in which the application is screened by the Board of Nursing and then forwarded to the Medical Board. It is recommended that CPP applications go to the Board of Pharmacy and then to the Medical Board for final approval.

What kind of qualifications should a pharmacist have to be a CPP? The North Carolina Center for Pharmaceutical Care (NCCPC) is an independent foundation comprised of the UNC School of Pharmacy, Campbell University School of Pharmacy, NC Society of Health-System Pharmacists, NC Chapter of the American Society of Consultant Pharmacists, and NC Pharmaceutical Association) is recommending applicants meet ONE of the options listed below for consideration as a CPP. In every case the CPP applicant must have a letter from a licensed physician who is willing to work collaboratively with the CPP, under the rules to be developed by the Medical Board and Board of Pharmacy.

1) Pharmacists who have earned Certification from the Board of Pharmaceutical Specialties or as a Certified Geriatric Practitioner.
2) A PharmD degree plus an American Society of Health-System Pharmacists accredited residency.
3) A PharmD degree plus one NCCPC approved certificate program.
4) A PharmD degree plus one year of experience, letters of recommendation from two physicians who are familiar with the applicant's clinical experience.
5) A BS degree in Pharmacy plus two NCCPC approved certificate programs.
6) A BS degree in Pharmacy plus three years of experience, letters of recommendation from two physicians who are familiar with the applicant's clinical experience.

What will be the standards for implementing a collaborative agreement?

1) The physician and CPP will have to agree to and sign copies of the pre-determined agreement and keep on file in their practice sites.
2) There must be a monitoring and review process in place in which the physician and CPP review and document patient outcomes from the collaborative agreement.
3) There must be communication between the physician and CPP on each patient to verify that physician-patient-CPP relationship is established and patient care information is exchanged in an on-going manner.
4) Patient care decisions or changes not specified in the collaborative agreement must be made by the physician.

These standards are similar to those for Nurse Practitioners.

Can collaborative agreements be made between groups of physicians and groups of CPP's?

In organized health care settings, such as a hospital, clinic, or defined practice management arrangement, a committee of physicians and CPP's ( eg. Pharmacy and Therapeutics Committee of a Hospital) can agree on standard collaborative agreements. Note that standards for verification of each physician-patient-pharmacist relationship and for outcomes monitoring and communication are the same as above.

I encourage North Carolina's pharmacists to review these carefully, as these regulations will have a significant impact on your professional life.

Sincerely,

Ron Small,
Co-Chair, NCAP Clinical Pharmacist Practitioner Act Task Force

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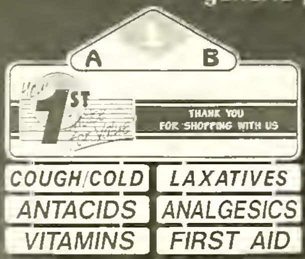

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# CAROLINA • JOURNAL OF • PHARMACY

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ASSOCIATION OF PHARMACISTS

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*We take the chill off the winter months with cheerful field of sunflowers. Photo courtesy of Sara Davis.*

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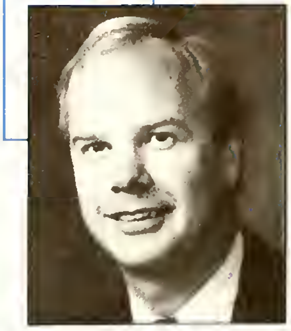
# DISCOVERING THE SPIRIT OF PHARMACY



Daniel G. Garrett
Executive Director

For more than 30 of his 50-odd years, Jimmy has worked delivering surgical supplies to the OR at Mission Hospital in Asheville. Jimmy was born with a development disability, and I had the privilege of getting to know him while I worked as the director of pharmacy at Mission St. Joe. But I learned that there was much more to him than his job *or* his disability.

One day, while I was in the office of another department director who was also a friend of Jimmy's, I noticed an interesting piece of art. It was a brightly colored pine board with a relief painting of seemingly random objects. On the back were intricate designs that were burned into the board. When I asked who the artist was, I found out it was Jimmy, and I was told that Jimmy would probably make one for me if I simply asked him to. One day while having lunch with Jimmy I asked him about his artwork. His eyes lit up and he asked me if I would like to have one. Obviously, I said yes. Nothing more was said and two months later, a piece of Jimmy's art was sitting in my office chair.

Jimmy and I got to know each other better after that, and several times I took him to lunch at restaurants that he liked, but had a hard time getting to. Jimmy did not drive and had to walk or take a bus wherever he wanted to go. He lived in Asheville because he liked the mountains, but he had never been to the top of Mount Pisgah. So one afternoon Jimmy and I left work early and bought sub sandwiches to eat at the top of Mount Pisgah. We set off on the 1.5 miles trail, and I asked Jimmy if he was ready because it was difficult walk. He responded with an ancient Chinese proverb – "a journey of a 1,000 miles starts with one step." So off we went, and soon I was having difficulty keeping up with Jimmy.

When we reached the summit we relaxed, ate our sandwiches, and enjoyed the sunset. Jimmy was ecstatic and said the view reminded him of Eagles Nest in Germany and the color of the sunset made him think of the volcano on the Island of Hawaii. Wow! Jimmy had been to Germany and Hawaii! I discovered a lot about Jimmy that evening, and he reminded me again that "a journey of a 1,000 miles starts with one step."

What does Jimmy have to do with the current state of pharmacy practice? I think Jimmy is an example that what we often perceive on the surface is very different than what we discover about what is present in the spirit. This is important to us as practitioners and to our perception of our current state of practice.

For years we have been hearing about the doom and gloom predicted for our profession. We experience evidence daily that we are overworked, medicines often cause more harm than good, the bottom line seems more important than the patient care and we don't get to use the knowledge that we worked so hard to learn. Over the past year I have been to twenty local pharmacy association meetings in the state. I begin each discussion by asking pharmacists to think about what they hoped to contribute as a pharmacist when they graduated from pharmacy school. The responses commonly include: to use my knowledge about drugs; to insure patient safety in using medicines; to be member of the health care team and community, and to help patients. This dialogue has helped me discover what is present in our professional spirit… to apply drug knowledge to improve health.

At these local meetings I then ask what are the barriers present that prevent us from doing what we really want to do as pharmacists. These answers come quickly: unreasonable workloads; insurance and managed care; lack of reimbursement for clinical services; apathetic pharmacists who just want a paycheck; systems which only focus on drug distribution; turf issues with other health care providers; lack of clinical training; laws and regulations which prevent us from using technicians; and lack of public awareness about what pharmacists are trained to do.

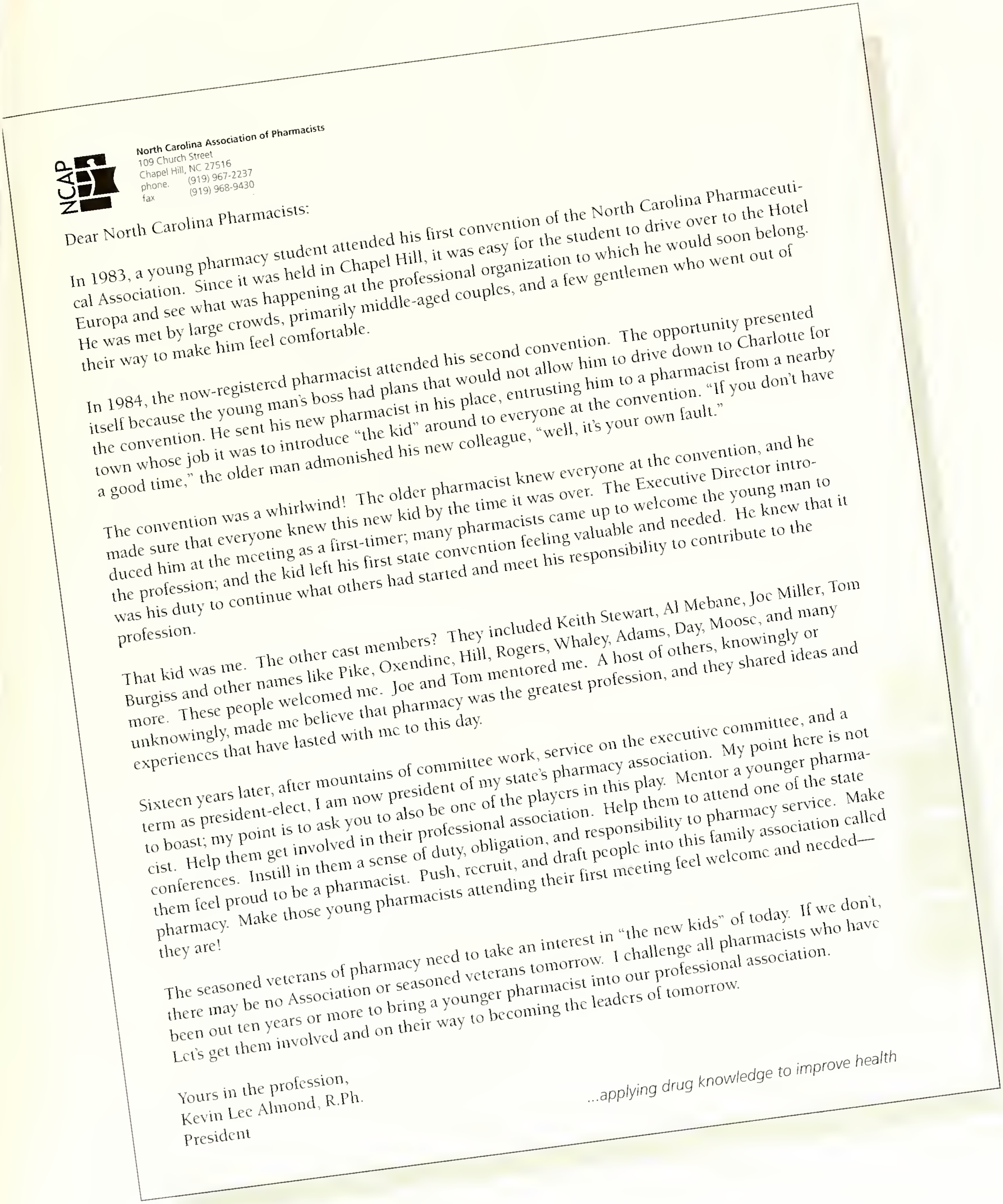
We are at the bottom of a steep trail with many obstacles in the way of achieving what we want to be in our spirit. I hope that each of you will look inside yourselves to re-discover your professional spirit, and by working together we can magnify our efforts to blaze a new path to our future.

And remember... a journey of a 1,000 miles starts with one step. Please choose the path you want to take and begin today.

*This article was excerpted from a speech given at the Annual Carolina Seminar, held in Greensboro on October 6 & 7, 1999. Dan Garrett can be reached at dan@ncpharmacists.org or (800) 852-7343*

### *How You Can Create Pharmacy's Future*

1. Join NCAP…the *Voice and Vision* for pharmacy.
2. Promote an enhanced role for pharmacy technicians and be a positive force to improve workplace conditions in your own pharmacy.
3. Create additional residency training opportunities in ambulatory care and work with students to help them learn how to manage dispensing and clinical services together.
4. Enlist physician support for the suggested regulations for the Clinical Pharmacist Practitioner (CPP) Act and reimbursement for CPP services.
5. Be a leader in your local pharmacy association and sign up to be a member of the NCAP speaker's bureau.
6. Join in the Floyd recovery effort and volunteer in the free clinic pharmacy in your community.
7. Connect the health care dots in your community and establish a Diabetes Community Health Project in your hometown.
8. Talk to patients and be a pharmacist by "applying drug knowledge to improve health."



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Dear North Carolina Pharmacists:

In 1983, a young pharmacy student attended his first convention of the North Carolina Pharmaceutical Association. Since it was held in Chapel Hill, it was easy for the student to drive over to the Hotel Europa and see what was happening at the professional organization to which he would soon belong. He was met by large crowds, primarily middle-aged couples, and a few gentlemen who went out of their way to make him feel comfortable.

In 1984, the now-registered pharmacist attended his second convention. The opportunity presented itself because the young man's boss had plans that would not allow him to drive down to Charlotte for the convention. He sent his new pharmacist in his place, entrusting him to a pharmacist from a nearby town whose job it was to introduce "the kid" around to everyone at the convention. "If you don't have a good time," the older man admonished his new colleague, "well, it's your own fault."

The convention was a whirlwind! The older pharmacist knew everyone at the convention, and he made sure that everyone knew this new kid by the time it was over. The Executive Director introduced him at the meeting as a first-timer; many pharmacists came up to welcome the young man to the profession; and the kid left his first state convention feeling valuable and needed. He knew that it was his duty to continue what others had started and meet his responsibility to contribute to the profession.

That kid was me. The other cast members? They included Keith Stewart, Al Mebane, Joe Miller, Tom Burgiss and other names like Pike, Oxendine, Hill, Rogers, Whaley, Adams, Day, Moose, and many more. These people welcomed me. Joe and Tom mentored me. A host of others, knowingly or unknowingly, made me believe that pharmacy was the greatest profession, and they shared ideas and experiences that have lasted with me to this day.

Sixteen years later, after mountains of committee work, service on the executive committee, and a term as president-elect, I am now president of my state's pharmacy association. My point here is not to boast; my point is to ask you to also be one of the players in this play. Mentor a younger pharmacist. Help them get involved in their professional association. Help them to attend one of the state conferences. Instill in them a sense of duty, obligation, and responsibility to pharmacy service. Make them feel proud to be a pharmacist. Push, recruit, and draft people into this family association called pharmacy. Make those young pharmacists attending their first meeting feel welcome and needed—they are!

The seasoned veterans of pharmacy need to take an interest in "the new kids" of today. If we don't, there may be no Association or seasoned veterans tomorrow. I challenge all pharmacists who have been out ten years or more to bring a younger pharmacist into our professional association. Let's get them involved and on their way to becoming the leaders of tomorrow.

Yours in the profession,
Kevin Lee Almond, R.Ph.
President

*...applying drug knowledge to improve health*

# INTRAVENOUS AMIODARONE (CORDARONE) FOR OUT-OF-HOSPITAL CARDIAC ARREST

by: Brian Robinette

Cardiac arrest is a devastating complication of cardiac disease with an estimated 250,000 to 350,000 episodes annually in the United States (1). Reported rates of survival for out-of-hospital cardiac arrest vary greatly and are dismal at best. Reported survival ranges from as high as 44% for patients with witnessed arrest secondary to ventricular dysrhythmias to a broader national average closer to 3% for unselected cases (2,3,4,5). Survival rates are highly dependent upon certain factors including witnessed vs. non-witnessed arrest, initiation of bystander Cardiopulmonary Resuscitation (CPR), response time of Emergency Medical Services (EMS), and arrhythmia classification at diagnosis (6). Out-of-hospital cardiac arrest is one of the leading causes of death in the U.S. making up a substantial portion of deaths due to cardiac causes. These figures point out the huge problem with this devastating complication and the dismal outcomes associated.

There have been no major advances in survival of out-of-hospital cardiac arrest since the institution of basic life support measures and early electrical defibrillation (1,7). One of the major hindrances to treatment is that only one-third to one-half of these events are witnessed. People with unwitnessed events generally have delayed institution of bystander CPR and delayed institution of Advanced Cardiac Life Support (ACLS) and defibrillation by EMS personnel. Victims with witnessed arrests are more likely to receive early bystander CPR within the first 5 minutes which doubles their chances of survival; however, only 20% of victims receive this life-saving therapy (8). Despite early bystander CPR and early defibrillation, only one-third of patients will survive to hospital admission, and only 3-13% of patients will survive to hospital discharge (7,9).

Improvement in survival to hospital admission is largely dependent upon early detection and initiation of CPR followed by early institution of ACLS including defibrillation by trained EMS technicians. Public education and CPR training in the general population are essential for improving patient outcomes. After bystander CPR, the arrival of EMS technicians is the next phase of treatment. Emergency medical technicians (EMTs) and paramedics are trained in the management of cardiac arrest. They institute or continue CPR, ACLS procedures, and facilitate transport to health care facilities. Most EMS programs have evolved over the last four decades into highly coordinated programs with EMTs arriving first at the scene and providing BLS support, and paramedics arriving shortly afterwards to initiate ACLS procedures and electrical defibrillation (4,10).

It is estimated that 60-85% of victims of out-of-hospital cardiac arrest will exhibit an initial rhythm of ventricular fibrillation (VF) or pulseless ventricular tachycardia (VT) (4). This incidence is significantly lower by the time most EMS personnel arrive on the scene with only 35-55% of victims exhibiting these rhythms, and the remainder in asytole or pulseless electrical activity (PEA) (11). Early electrical defibrillation is the preferred therapy to terminate VF/VT. Survival is excellent when these measures can be instituted within the first few minutes of a cardiac arrest (12). Unfortunately, most out-of-hospital cardiac arrest victims do not receive therapy this quickly. These dysrhythmias rapidly consume myocardial energy reserves causing the heart to deteriorate into asystole. The likelihood for successful defibrillation is reduced by about 10% with each minute from collapse to initiation of CPR or defibrillation. Defibrillation energy also increases over time, making successful cardioversion more difficult (13). A time interval of more than 10 minutes from collapse without CPR or defibrillation renders that victim virtually impossible to successfully defibrillate.

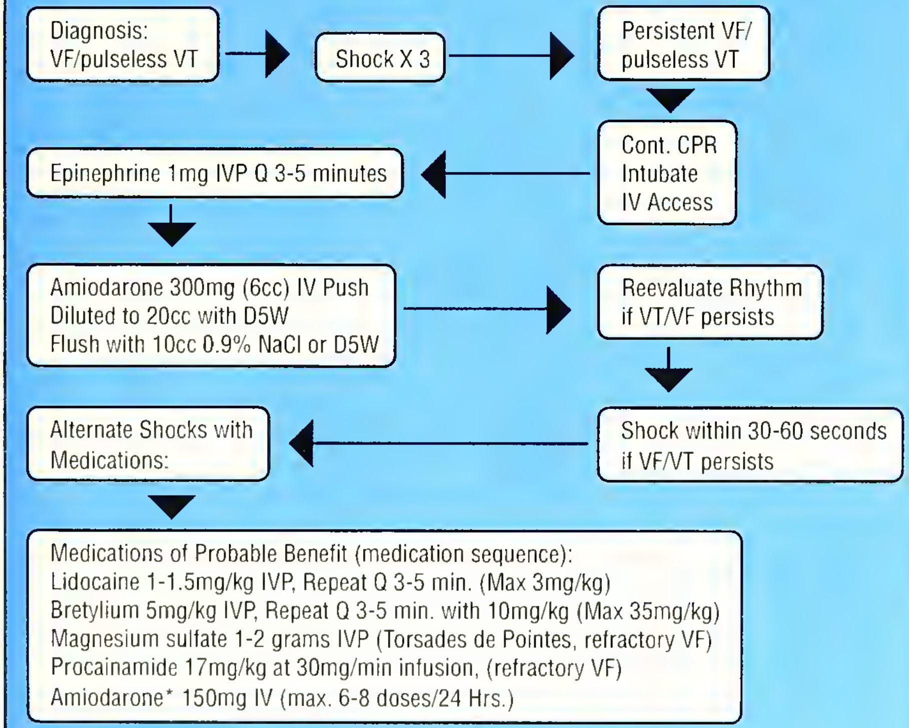
Demonstrating benefits of medication administration during cardiac arrest has traditionally been difficult. The majority of information has been extrapolated from animal models. Testing human response is fraught with problems. There is a lack of well designed, placebo-controlled trials using drug therapy in this setting. Human data with epinephrine, bicarbonate, calcium, lidocaine, and bretylium have proven equivocal even though animal data suggests benefit (11,12,14). The addition of well designed clinical trials to evaluate medication therapy on survival is essential to improve therapy selection and timing of pharmacologic agents. Extrapolation of data from clinical trials in patients surviving sudden cardiac death may provide clues to choosing pharmacologic agents to study.

Limited data with antidysrhythmic agents lidocaine and bretylium have been inconclusive in the setting of cardiac arrest and CPR administration (15,16,17,18,19). Intravenous amiodarone, a class III antidysrhythmic agent, may be a superior alternative to traditional antidysrhythmic agents used in cardiac arrest situations. Data from clinical trials using intravenous (IV) amiodarone in patients with malignant ventricular arrhythmias conclude that amiodarone reduces the rate of sudden cardiac death in high-risk patients with acute myocardial infarction (AMI) or congestive heart failure (20,21). Recently a meta-analysis of randomized trials of IV amiodarone has shown a 13% overall reduction in mortality (22). Intravenous amiodarone was consistently effective in terminating these lethal dysrhythmias in the majority of patients studied. These data suggest that IV amiodarone may be beneficial when used in patients experiencing cardiac arrest secondary to malignant ventricular dysrhythmias.

Recent evidence from the Amiodarone in Out-of-Hospital Resuscitation of Refractory Sustained Ventricular Tachyarrhythmias (ARREST) trial is changing the way that EMS units are treating out-of-hospital cardiac arrest (23). This pivotal study was performed in Seattle, and surrounding King County, Washington. The study was designed to test the hypothesis that IV amiodarone would increase the number of victims surviving to hospital admission. This was a double-blind, randomized, placebo-controlled study conducted between November 1994 and February 1997. Patients with ongoing VT/VF received standard CPR and defibrillation with 3 shocks, intubation, IV access and Epinephrine administration . They were then randomized to IV amiodarone as a 300mg rapid IV peripheral infusion, or infusion of its diluent, (placebo). The contents of one 6 ml amiodarone vial were drawn into a sterile syringe and diluted to a total volume of 20 ml using Dextrose 5% water (D5W). After amiodarone administration, the standard ACLS algorithm was then followed including the administration of other antidysrhythmic agents if needed. There were 504 patients included in the trial with 246 receiving IV amiodarone and 258 receiving matching placebo.

The addition of IV amiodarone to standard ACLS protocols in the ARREST trial increased the numbers of patients admitted alive to the hospital from 34% to 44% (p=0.03) for the group as a whole, a 29% relative increase. When patients experiencing VF arrest were singled out (83% of the cohort), survival to hospital admission increased from 39% to 49% with amiodarone, a 25% relative increase. Even more impressive was a 56% relative increase in survival observed in patients experiencing return of spontaneous circulation (ROSC) prior to drug administration (64% vs. 41%). A nonsignificant trend towards less concomitant antidysrhythmic drug treatment in the amiodarone group, 66% vs. 73% (p=0.13) was also noted. More patients in the placebo group had witnessed arrest (77% vs. 70%), however, more patients receiving amiodarone received bystander CPR (68% vs. 59%). Administration of study drug averaged 20 minutes from EMS dispatch for each group. Survival correlated closely with time from dispatch to receipt of study drug for both groups with amiodarone being superior at all time points.

**Figure 1.** Treatment Algorighm for Patients experiencieng Cardiac Arrest secondary to


Diagnosis: VF/pulseless VT
Shock X 3
Persistent VF/ pulseless VT
Cont. CPR
Intubate
IV Access
Epinephrine 1mg IVP Q 3-5 minutes
Amiodarone 300mg (6cc) IV Push
Diluted to 20cc with D5W
Flush with 10cc 0.9% NaCl or D5W
Reevaluate Rhythm if VT/VF persists
Shock within 30-60 seconds if VF/VT persists
Alternate Shocks with Medications:
Medications of Probable Benefit (medication sequence):
Lidocaine 1-1.5mg/kg IVP, Repeat Q 3-5 min. (Max 3mg/kg)
Bretylium 5mg/kg IVP, Repeat Q 3-5 min. with 10mg/kg (Max 35mg/kg)
Magnesium sulfate 1-2 grams IVP (Torsades de Pointes, refractory VF)
Procainamide 17mg/kg at 30mg/min infusion, (refractory VF)
Amiodarone* 150mg IV (max. 6-8 doses/24 Hrs.)

*Supplemental doses were not evaluated in ARREST study or included in current ACLS guidelines, but is considered standardcare in patients with persistent ventricular dysrhythmias and should be considered early in drug therapy selection.

The choice of the 300mg dose in the setting of a cardiac arrest was largely empiric. Given the lipophilicity, large volume of distribution of amiodarone, and relatively poor circulatory support of CPR, the dose chosen was double the normal bolus dose of 150mg in traditional IV amiodarone administration protocols (24). This dose may be a relative underdose due to factors effecting peripheral administration during CPR which may compromise central circulatory concentrations of drugs (25). Future studies should address using higher doses and/or repeat doses or infusions. The inability to start amiodarone infusions or give additional bolus doses in the ARREST study brings into question the additional benefit with these measures.

There are several important concerns with the ARREST study. One is the relatively small sample size. There were 3954 victims treated for cardiac arrest during this time period, but only 504 patients met eligibility criteria for enrollment representing 13% of the entire population treated. Because of rapidly changing clinical circumstances during resuscitation, many patients who may have received benefit were not treated because they did not meet initial inclusion criteria. Generalizing this data to the entire cardiac arrest population as a whole should be avoided. Intravenous amiodarone should be reserved for those patients meeting enrollment criteria which included non-traumatic cardiac arrest due to ventricular dysrhythmias after treatment with 3 or more precordial shocks have failed, IV access, endotracheal intubation are established, and IV epinephrine is administered.

Another major concern with the study is the inability to detect significant effects on survival to hospital discharge and neurologic outcomes. The study was not powered to detect significant changes in these important end-points. Disappointingly the study failed to show trends towards improved survival to hospital discharge even when specific subgroups were examined. Future work needs to be performed to answer these

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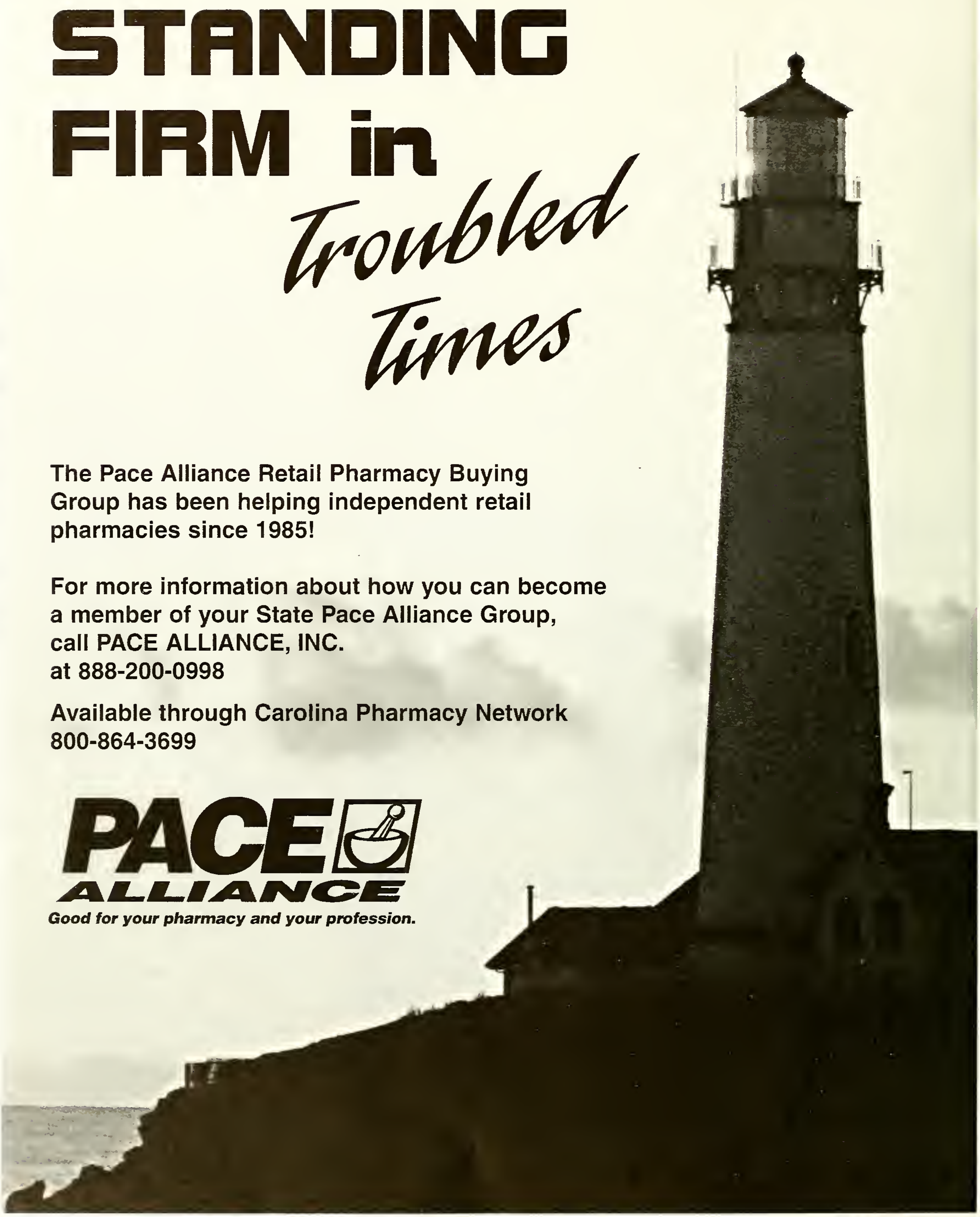

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*Continued from page 7*

important questions.

The Amiodarone versus Lidocaine in Pre-hospital Refractory Ventricular Fibrillation trial (ALIVE) is currently enrolling patients to answer some of these important questions. This is a randomized, placebo-controlled, double-dummy comparison of amiodarone and lidocaine. Patients will receive placebo, lidocaine 1mg/kg, or amiodarone 5mg/kg to assess their effects on ROSC and survival to hospital admission.

Intravenous amiodarone is not currently included in ACLS guidelines (26), nor is it currently included in the 1998 European Resuscitation Council (ERC) guidelines for Adult Advanced Life Support (27). These bodies have not met since the completion and reporting of the ARREST trial, and revisions are expected in the near future. The ACC/AHA Committee on the Management of Acute Myocardial Infarction does recommend IV amiodarone as a beneficial, useful, and effective agent for the treatment of sustained monomorphic VT in AMI patients not accompanied with chest pain, pulmonary congestion or hypotension (28). In Europe, the European Resuscitation Council (ERC) recommends IV amiodarone in the treatment of peri-arrest broad complex tachycardia refractory to electrical counter-shocks and lidocaine (29). These guidelines are warranted since IV amiodarone is superior to bretylium and less likely to produce hypotension than procainamide or bretylium.

In response to this data, clinicians at NorthEast Medical Center evaluated the addition IV amiodarone to our current ACLS protocol both for out-of-hospital patients as well as hospitalized patients experiencing cardiac arrest secondary to VF/VT. The data was reviewed in February, 1999 by the Department of Emergency Services and Cardiac Care Committees. After available information was evaluated, the decision was made to include IV amiodarone on our ACLS algorithm and improve access to IV amiodarone system wide. Ampuls of IV amiodarone were placed in PYXIS, machines in strategic locations throughout the medical center. Since not all cardiac arrests occur in close proximity to a PYXIS machine, a package of two vials (150mg/vial) of amiodarone was prepared for the code response team to physically carry to each cardiac arrest event to further ensure that IV amiodarone was available to all cardiac arrest patients. The high cost of IV amiodarone was another major issue for these stocking decisions.

The addition of IV amiodarone was also approved for EMS usage for patients experiencing out-of-hospital cardiac arrest from documented VF/VT. Intravenous amiodarone is packaged as 150mg glass ampuls containing 3 ml of diluent, thus two ampuls (300mg) are required for each dosage. Amiodarone vials are glass, so packaging that prevented breakage while stored in the chaotic environment on an ambulance was also a major concern. Intravenous amiodarone is mixed with a soaplike substance, polysorbate 80, to enhance viscosity. Foaming or breakdown of the active drug was another concern which could cause the drug to be ineffective or rendering the drug difficult to draw-up into a syringe for rapid parenteral injection. The last concern was related to the stability of IV amiodarone in an environment of constant motion on the ambulance. Experience from the Richmond, Virginia EMS service suggests that the agitation from vehicle motion does not effect the stability of IV amiodarone and does not effect its ability to be drawn up in a syringe (30).

Since institution of the program in February, 1999, our institution has used IV amiodarone multiple times for cardiac arrest due to VF/VT. The majority of use has occurred in patients experiencing cardiac arrest in the hospital or Emergency Care Center settings either for a new onset cardiac arrest or continuation of a cardiac arrest begun in the field. A smaller number of patients have received IV amiodarone in the field for out-of-hospital cardiac arrest. Current usage appears low primarily due to the short duration of our program, and the learning curve involved in instituting the program and educating health care providers. The ultimate goal is to treat all eligible patients with this potentially life-saving therapy.

Several problems with the system have been identified after examining early usage trends. The appropriate dose of IV amiodarone in the cardiac arrest setting is 300mg. Many patients have received 150mg IV doses similar to the manufacturers recommended initial bolus dose for treatment of life-threatening ventricular dysrhythmias (24). This most likely represents a relative underdose in this patient population (25). Appropriate patient selection is another important factor.

*Continued on page 11*

**Table 1.** IV Amiodarone administration recommendations during cardiac arrest

| | |
|---|---|
| Bolus dose | Amiodarone 300mg (6ml) diluted to 20ml using D5W administered as a rapid IV injection.<br>Flush with 10 ml of 0.9% NaCl or D5W. |
| Supplemental doses* | Amiodarone 150mg (3ml) diluted to 20ml using D5W administered as a rapid IV injection.<br>Flush with 10 ml of 0.9% NaCl or D5W |
| Loading Infusion | Amiodarone 360mg over 6 Hours (1 mg/min.) (34cc/hr)<br>Admix 900mg (18ml) in 500ml of D5W or NS (Final conc.=1.8mg/ml) |
| Maintenance Infusion | Reduce infusion rate to 0.5mg/min (17cc/hr). |

* Supplemental doses were not evaluated in ARREST study or included in current ACLS guidelines, but is considered standard care in patients with persistent ventricular dysrhythmias and should be considered early in drug therapy selection.

**Table 2.** Y-site compatibilities of IV Amiodarone with other emergency medications:

| | |
|---|---|
| Compatible medications: | Bretylium tosylate, Dopamine, Dobutamine, Esmolol, Isoproterenol, Lidocaine, Nitroglycerin, Norepinephrine, Phenylephrine, Potassium, Procainamide, Regular Insulin |
| Incompatible Medications: | Sodium bicarbonate (forms precipitate), Aminophylline, Heparin |
| No information available: | Atropine, Epinephrine, Calcium Chloride, Nitroprusside, Magnesium Sulfate |

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*Continued from page 9*

Many patients who have VF/VT as their presenting arrhythmia do not receive IV amiodarone. Factors such as inexperience with its use or lack of knowledge of benefit are the primary reasons for underusage. Another patient selection concern is usage in patients experiencing cardiac arrest without VF/VT as their presenting arrhythmia. It is not known if administering IV amiodarone to these patients will be beneficial and should be avoided. Lastly, timing of administration is critical for its effectiveness. The average time from EMS dispatch to drug administration in the ARREST study was 20 minutes which is relatively late in a cardiac arrest (23). These data also show a time-dependent effect on benefit with significantly better survival benefit achieved with administration less than 16 minutes from EMS dispatch. Many patients receive amiodarone well into a cardiac arrest where the benefit is less evident. Education of health care providers is key to change thought processes involved during cardiac arrest procedures to administer amiodarone earlier during the course of events.

Several major medical centers have incorporated the ARREST data into clinical practice by adding IV amiodarone to standard ACLS protocols administered by EMS services including Seattle and surrounding King county, Washington, and the city of Richmond, Virginia. Many more medical centers will begin to incorporate this therapy into standard ACLS procedures in the near future. Incorporation into ACLS guidelines in the U.S. and worldwide will certainly take place in the near future as these bodies meet periodically to revise guidelines. Until such time, each institution must evaluate the available data and make decisions on their use of IV amiodarone for cardiac arrest patients experiencing ventricular dysrhythmias. Ongoing research should help to solidify the position of IV amiodarone in the armamentarium of medications useful for treating this devastating event. ◉

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30. Ornato JP. Emergency resuscitation of shock resistant out-of-hospital cardiac arrest. In: The Protocols series: Guidelines from experts in arrhythmias. Galen press. 1998Figure 1. Treatment Algorithm for Patients experiencing Cardiac Arrest secondary to ventricular dysrhythmias.

## About the Author

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*Students package food and supplies for flood victims.*

# UNC Pharmacy Students Pitch-In With Floyd Relief

Pharmacy students at UNC-CH have been working overtime to help flood victims in eastern North Carolina. Immediately after Hurricane Floyd hit, the student organization Taking Action By Service (TABS) sponsored a food and supplies drive within the School of Pharmacy, collecting and delivering over two carloads of donations to the N.C. Foodbank. The School's academic and drug development fellows volunteered their time and efforts in Kinston, working to distribute much-needed supplies at an old Lowe's warehouse off Hwy 70. The fellows also took with them medical supplies that they collected themselves and food and drinks donated by the UNC Pharmacy Alumni Association.

Four of the School's pharmacotherapy residents traveled to Tarboro and Kinston where they provided a number of services to people affected by the flooding. In addition to bringing sample medications and diabetic supplies with them, they also brought a computer with on-line medical references so they and other health care professionals could answer patients' questions and provide better treatment. The residents organized temporary pharmacies from available medications, administered vaccines, checked blood-pressure and blood glucose concentrations and provided drug information to patients.

A new initiative begun at the School of Pharmacy is the Emergency Pharmaceutical and Medical Supplies Hotline. Commencing operation on October 1, the hotline accepts donations of pharmaceutical and medical supplies from pharmaceutical companies, doctors' offices, drug stores, medical supply companies, and others within the state and around the nation for distribution to flood-ravaged communities. If you would like to make a donation, the hotline number is (919) 843-7854. Students from all five UNC-CH health affairs schools are staffing hotline phones, which have been provided by the Area Health Education Centers (AHEC) program. School of Pharmacy students and staff are organizing and preparing the donations for distribution.

## Fall 2000 Applications for UNC-CH External Doctor of Pharmacy Program

The University of North Carolina at Chapel Hill School of Pharmacy will be accepting applications for the sixth entering class of the External Doctor of Pharmacy Program from February 1 through May 1 for the Fall 2000 Semester. Applications will be available on January 1. This Program will continue to admit students as long as sufficient interest remains to sustain the Program. Therefore, those pharmacists interested should not delay in applying. If you would like a brochure, an application, or additional information about the Program, contact:

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## State of the art:

# NEW HIV ANTIRETROVIRAL THERAPY

by: Melissa D. Johnson

Therapeutic options for patients infected with human immunodeficiency virus (HIV) have expanded dramatically in recent years, with fourteen antiretroviral compounds now approved for use in the United States. The most recent additions to the antiretroviral armamentarium include abacavir (Ziagen), amprenavir (Agenerase), and efavirenz (Sustiva). While these new drugs expand the therapeutic options available to patients, a cure for HIV still eludes researchers and HIV-infected patients continue to die from this fatal disease. Highly active antiretroviral therapy regimens (HAART) continue to be complicated and represent significant challenges to the patient and practitioner with their associated toxicities and drug interactions. As we approach the new millennium, researchers continue to explore new strategies to improve outcomes among patients infected with HIV, including development of new pharmacologic agents, protease-sparing regimens, scheduled treatment interruptions, resistance assays, and immune-based strategies.

## New Antiretrovirals: No Magic Bullets

### *Abacavir*[1]

Abacavir is the first guanosine analogue reverse transcriptase inhibitor. It is approved for use in both adults and children, with the usual adult dose as 300 mg (one tablet) every twelve hours. It is also available as an oral liquid form (20 mg/ml) that may ease administration for children and others who have difficulty swallowing. Abacavir is generally well tolerated with nausea and vomiting, diarrhea, anorexia, fever, rash, and insomnia/sleep disorders reported as the most common side effects in clinical trials. Abacavir has been associated with a potentially fatal hypersensitivity reaction among three percent of patients. This reaction is characterized by a constellation of symptoms including fever and rash, malaise, fatigue, nausea, vomiting, or diarrhea, which usually occurs within the first four weeks of therapy and resolve rapidly upon discontinuation of abacavir. Patients with symptoms that could potentially represent abacavir hypersensitivity should be closely followed by their physician and/or pharmacist and carefully monitored before stopping abacavir. Patients with suspected hypersensitivity who have stopped abacavir therapy should never be rechallenged, since rechallenge has been associated with a fatal anaphylactic reaction.

Since it is not significantly metabolized by the cytochrome P450 system, abacavir has few clinically significant drug interactions. It is metabolized via alcohol dehydrogenase, however, and in one single dose study of coadministration with ethanol in HIV-infected men resulted in a moderate increase in abacavir serum concentrations (AUC increased 41%) and half-life (26%). Resistance to abacavir has been reported in vitro and in some clinical trials. The most common resistance mutations reported among clinical isolates include M184V (which is also associated with resistance to lamivudine) and L74V, although the clinical relevance of such mutations has not been established.

### *Amprenavir*[2]

Amprenavir is a potent inhibitor of HIV protease approved for use in adults and children. It is usually dosed in adults as 1200 mg (eight 150 mg soft-gel capsules) every twelve hours. It is also available as 50 mg soft gel capsules and 15 mg/ml oral solution. Amprenavir may be administered with or without food, but since a high fat meal decreases absorption of amprenavir, this should be avoided.

Like most other protease inhibitors, amprenavir inhibits CYP 3A4, and interacts with numerous other medications, including astemizole, bepridil, ergotamine, midazolam, and triazolam. When administered concomitantly, rifampin may decrease amprenavir peak serum concentrations (Cmax), area under the curve (AUC), and minimum serum concentrations (Cmin) by 70%, 82%, and 92% respectively. Concomitant administration with these agents, is therefore, not recommended. In addition, serum concentration monitoring is recommended for amiodarone, lidocaine, tricyclic antidepressants, and quinidine when administered with amprenavir. Amprenavir may elevate serum concentrations of sildenafil (Viagra), and patients taking both agents should be advised of the potential for increased in sildenafil-associated adverse events such as hypotension, visual changes, and priapism.

In clinical trials the most common adverse events among patients taking amprenavir were gastrointestinal events (nausea, vomiting, diarrhea, taste disturbances), skin rashes, and paresthesias (oral, perioral, and peripheral). As with other protease inhibitors, amprenavir therapy may be associated with alterations in glucose tolerance, hyperlipidemia, and fat redistribution.

Resistance has been reported with amprenavir, and has been associated with a unique primary mutation at 150V, although the clinical significance of this remains to be demonstrated. Other mutations that confer resistance to amprenavir, including point mutations at codons 46 and 47, have also been associated with cross-resistance to other protease inhibitors.

### *Efavirenz*[3]

Efavirenz is a potent non-nucleoside reverse transcriptase inhibitor (NNRTI) approved for use in both adults and children. Its usual adult dose is 600 mg (three 200 mg capsules) daily. The manufacturer recommends administering efavirenz at bedtime, since it has been associated with central nervous system effects such as dizziness in clinical trials.

Interestingly, efavirenz is both a CYP450 enzyme inducer and inhibitor. Generally, drug interactions may occur with concomitant administration of compounds that are metabolized by CYP2C19, 2C9, and 3A4. In addition, coadministration of efavirenz and inducers

*Continued on page 15*

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of CYP3A4 may result in lower efavirenz serum concentrations. Like amprenavir, efavirenz coadministration with astemizole, cisapride, midazolam, triazolam, and ergot derivatives is contraindicated due to the potential of increased serum concentrations and associated life-threatening adverse events.

In clinical trials, the most frequent adverse events associated with efavirenz therapy include nausea, rash, dizziness, impaired concentration, and sleep disturbances such as insomnia and abnormal dreams. 52% of 2215 patients taking efavirenz in clinical trials reported central nervous system and psychiatric symptoms, but only 2.6% were severe and disrupted the patient's daily activities. Resistance to efavirenz is often associated with the K103N mutation, which appears to confer cross-resistance among all available NNRTIs.

Risk-benefit must be carefully considered before using efavirenz in pregnant women since efavirenz has been associated with birth defects in studies with cynomologous monkeys. However, other antiretroviral agents have not been studied in the primate model and all antiretroviral agents, including efavirenz, are classified as FDA pregnancy category B or C.

## In the pipeline

There are several promising antiretrovirals currently in clinical trials, including emivirine, tenofovir, ABT-378, and T-20 (Table 1). These may offer additional therapeutic options as components of initial and "salvage" regimens for HIV-infected patients.

## Treatment Strategies

With the introduction of protease inhibitors in 1996 and the publication of positive findings from clinical trials containing triple-drug-combinations including a protease inhibitor, highly-active antiretroviral therapy has become the standard of care for HIV-infection. The US Public Health Service has convened panels of experts and published recommendations for antiretroviral therapy in HIV-infected adults and adolescents. These guidelines were last updated in the spring of 1999 and are currently available in draft format on the HIV/AIDS Treatment Information Service website (http://www.hivatis.org).

## Protease-sparing regimens

Since HAART has become widely implemented, mortality rates in HIV-infected adults in the United States have dropped more than 70%. These therapies are complicated, however, and may be associated with adverse events such as lipodystrophy, fat redistribution, and altered glucose tolerance. The development of newer agents such as abacavir and efavirenz has led to a reexamination of the potency of "protease-inhibitor-sparing" regimens, or combinations containing three or more NRTIs or NNRTIs. Results from several comparative clinical trials in relatively inexperienced patients were recently presented at the 39th Interscience Conference of Antimicrobial Agents and Chemotherapy (ICACC).[4] In CNA3005, a regimen of abacavir plus lamivudine/zidovudine (Combivir) was compared to indinavir plus lamivudine/zidovudine (Combivir) in a randomized, double-blinded placebo-controlled fashion. All 562 study participants were antiretroviral therapy naïve and were required to take 16 tablets per day during the study. After week 16, those with HIV RNA >400 copies/ml could change to open-label therapy. Results were available from 55% of subjects in the abacavir arm, and 45% of those in the indinavir arm who had completed 48 weeks of therapy. Similar immunologic benefit was observed among both groups in the study, with increases in CD4+ cell count of 149 cells/$mm^3$ in the abacavir arm and 142 cells/$mm^3$ in the indinavir arm after 48 weeks of therapy. By intent-to-treat analysis, similar numbers of subjects (51%) in each treatment arm achieved virologic suppression to less than 400 copies/ml. However, more patients in the indinavir-containing arm achieved viral suppression below 50 copies/ml ( 46% vs. 40%), and among patients with a high baseline viral load (>100,000 copies/ml) the indinavir containing regimen was associated with significantly better rate of virologic suppression to less than 50 copies/ml (45% vs. 31%). Thus, while the protease-sparing regimen of abacavir-combivir is attractive for its compactness (i.e., requiring only two tablets every 12 hours) and overall safety profile, an indinavir-containing regimen may be more potent for those with baseline viral loads above 100,000 copies/ml. [4]

> *There are several promising antiretrovirals currently in clinical trials, including emivirine, tenofovir, ABT-378, and T-20*

Results of a large, open-label, randomized, multicenter, international clinical trial comparing efavirenz/lamivudine/zidovudine and indinavir/lamivudine/zidovudine were also recently presented. To be eligible for study participation, subjects could have no prior exposure to lamivudine, any NNRTI, or any protease-inhibitor. After 72 weeks of therapy in intent-to-treat analysis, 67% of subjects in the efavirenz arm achieved virologic success with a viral load <400 copies/ml, compared to only 44% of those in the indinavir arm ($p<0.05$). Subjects receiving efavirenz were also significantly more successful than those receiving indinavir in achieving viral suppression to <50 copies/ml (60% vs. 40%, $p<0.05$). Importantly, virologic success with the efavirenz-containing regimen was also demonstrated for patients with a high baseline viral load (>100,000 copies/ml). In addition, significantly more subjects in the indinavir arm discontinued therapy due to adverse events than those in the efavirenz arm (23% vs. 7%). While impressive, the results in favor of efavirenz in this study must be considered in the context of the open label study design and the dramatically different pill burden between study arms (7 pills in the efavirenz regimen compared to 16 in the indinavir regimen). However, demonstration of virologic efficacy of a "protease-sparing" regimen among patients with a high baseline viral load and long term durability of this regimen are quite encouraging. [5]

Other trials have demonstrated effectiveness of other "protease-sparing"

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# ANNUAL CAROLINA SEMINAR 1999

*Vicki Ripley - Pearls on the joy of reducing missed doses.*

*Karen Campbell, LeAnne Kennedy and a new member for the palm pilot drawing.*

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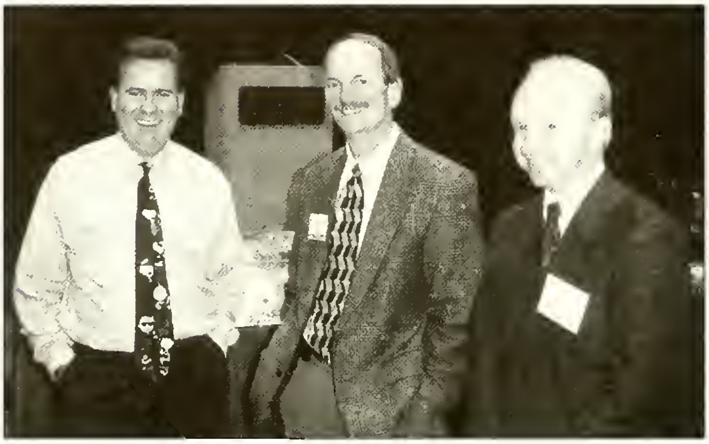
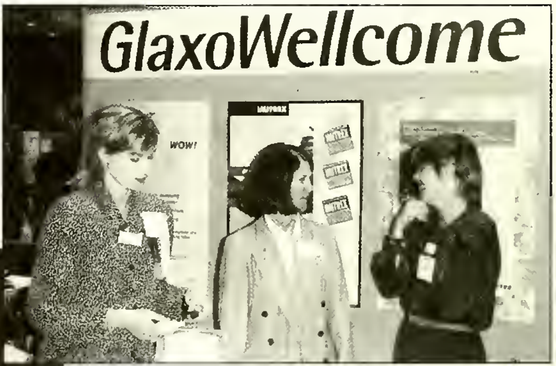


*Reggie Hillman of Amgen, NSHP Member David Wheeler, and Bob Pollard of Amgen.*



*Lynne Kearns of Glaxo, Board Member Lynn Alexander, and Phyllis Braswell of Glaxo.*

*Fred Eckel, Mike Cashion of Glaxo, Phil Milam of Bayer, and NCSHP Treasurer John Kessler attend the reception for Platinum Sponsors.*

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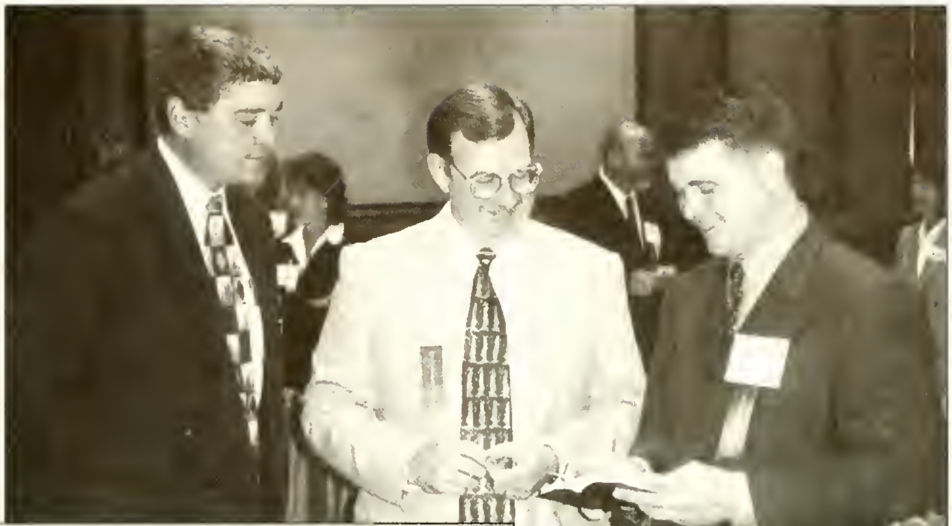

*Mark Mendenhall of ESI, NCSHP past president Steve Novak, and Jay Brower of ESI.*

*Last NCSHP Meeting - Vance Collins, Steve Novak, John Kessler, Joe Johnson, Bill Harris, Dennis Williams, Fred Eckel, Beth Early, Lynne Alexander, Jane Younts, and Julie Kirk.*

*Regina Schomberg and Jim Beardsley of the Mentorship Program.*

*Jim Hasspacher - Pearl on the extraterrestrial search for medication errors.*

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*Continued from page 15*

regimens, including stavudine/didanosine/lamivudine and stavudine/didanosine/nevirapine with early reports of success.[6] However, protease-containing regimens continue to be recommended first-line by the USPHS, primarily because of the extensive efficacy data with these regimens and historical lack of efficacy data with protease-sparing regimens.

## Salvage Therapy

Treatment options for patients failing standard therapy continue to be limited. Limited data are available to support four or five or more drug-containing regimens in extensively-experienced patients. Regimens containing up to 8 or 9 antiretrovirals have been used in Europe, and are termed "Mega HAART." Although early data from Mega-HAART trials suggests that these regimens may have some virologic benefit among patients with extensive ART experience and resistance, use of these regimens is limited by the complexity of drug interactions, pill burden, and drug toxicities.

## Scheduled Treatment Interruptions

Other new strategies are increasingly being studied in attempts to maximize the host's immunologic response to HIV infection and improve durability of virologic and immunologic responses to therapy. Scheduled treatment interruptions (STIs) or planned drug holidays may boost host HIV-specific immune responses, provide information about HIV pathogenesis and immune responses, enable repopulation of sensitive viral strains, and enable reduction or elimination of treatment-associated adverse events. Most patients who suspend drug therapy experience rapid viral rebound, although they usually respond to re-initiation of antiretroviral therapy. More concerning, however, are data indicating that many patients experience a decline in CD4+ cell count during STI. There are also theoretical concerns that increased viral replication during the treatment-free interval could enable re-seeding of latent reservoirs and extend the time to viral eradication, and that viral resistance may develop rapidly upon re-initiation of antiretroviral therapy.

## Genotypic and Phenotypic Analyses to Guide Therapy

Drug-resistance testing in the form of genotypic and phenotypic assays is increasingly available to researchers and clinicians in developed nations. As often happens, the pace of technological development rapidly exceeds our ability to determine the role of new technologies in the clinical practice setting. Until now, treatment history and presumed cross-resistance patterns have been the cornerstone of selecting a new antiretroviral regimen for more experienced patients. Genotypic and phenotypic assays increase the options available to clinicians when facing the challenge of selecting therapy for a patient with probable drug resistance. The advantages and disadvantages of these assays are many (Table 2). Recently, a randomized, controlled clinical trial in treatment-experienced patients demonstrated that genotypic-resistance testing had a significant benefit in virologic response compared to control. (mean difference 0.48 log [0.01-0.97], p=0.05).[7] Because of economic considerations and limitations of current assay technologies, however, further studies are necessary to better define the role of resistance assays and to identify subpopulations of patients in whom resistance testing has the greatest benefit.

## Immune-based Strategies

HAART therapy was hoped to help control viral replication and allow a sufficient period of time for latently

*Continued on page 21*

**Table 1:** The Antiretroviral Pipeline

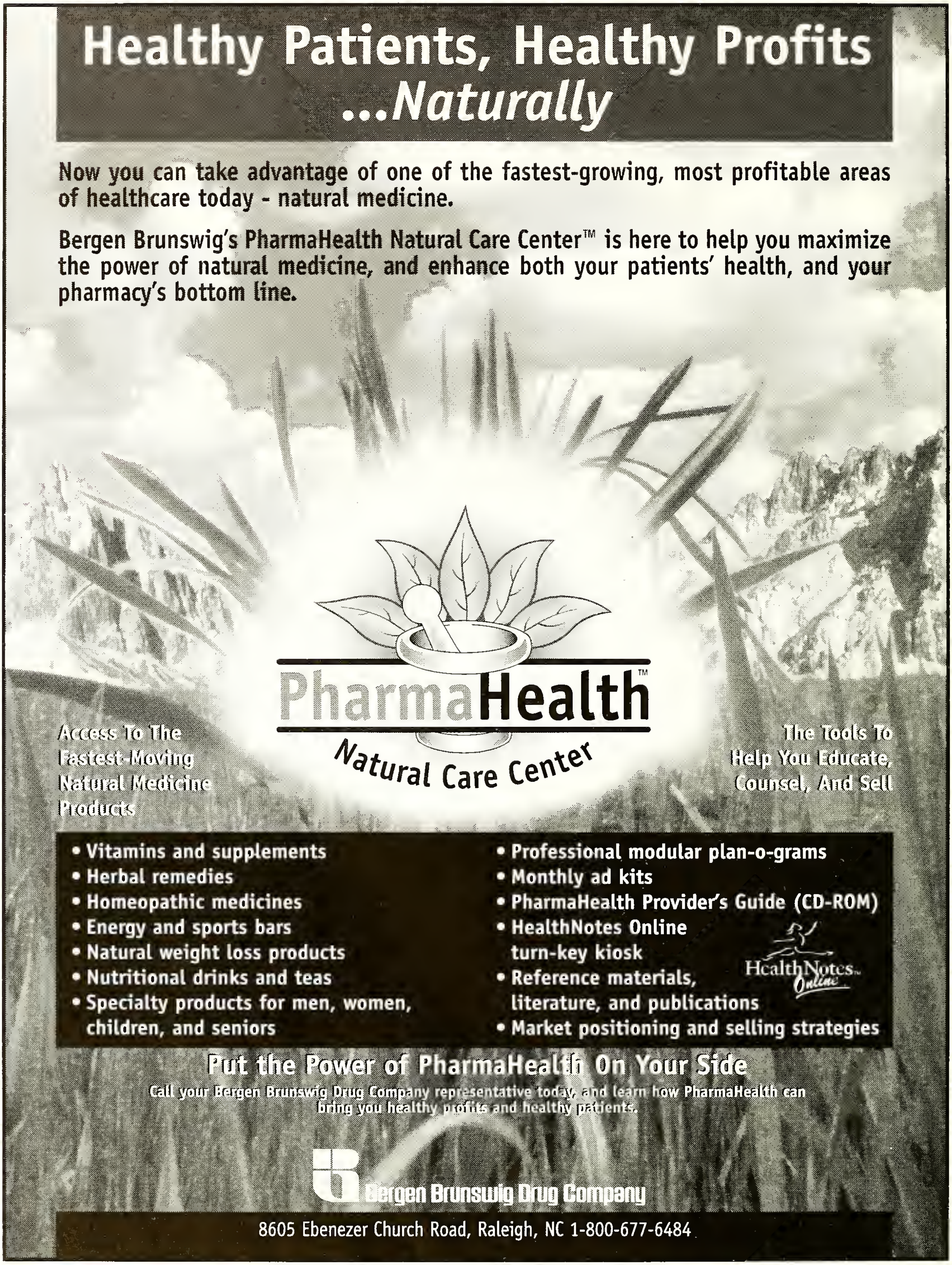
| NRTI's | NNRTI's | PI's | Other Classes |
|---|---|---|---|
| abacavir | delavirdine | amprenavir | Fusion Inhibitor: T-20*, T1249* |
| didanosine | efavirenz indinavir | Nucleotide | RTI: adefovir*, tenofovir* |
| lamivudine | nevirapine | nelfinavir | Receptor blockers: |
| stavudine | GW420867X* | ritonavir | TAK-779,AMD3000 |
| zalcitabine | emivirine* | saquinavir | |
| zidovudine | | ABT-378* | |
| DAPD* | | tipranavir* | |
| dOTC* | | | |

* under development
NRTI= nucleoside reverse transcriptase inhibitor
NNRTI= non- nucleoside reverse transcriptase inhibitor
PI= protease inhibitor
RTI= reverse transcriptase inhibitor

**Table 2:** Advantages and Disadvantages of Resistance Assays

| Type | Advantages | Disadvantages |
|---|---|---|
| Genotypic | Relatively simple to perform<br>Widely available<br>Relatively rapid turn-around time<br>Enable early detection of sentinel mutations before to change in phenotype | Unable to detect minor variants<br>Interpretation requires prior knowledge of genetic determinants of resistance<br>Cannot predict effect of mutational interactions on phenotype |
| Phenotypic | Assess "net" effect of mutations on drug susceptibility<br>Provide data on cross-resistance | Unable to detect minor variants<br>Time-consuming to perform<br>Relatively expensive<br>Complexity of the assays limits<br>Not widely available<br>Slow turn-around time |

Adapted from:. Kuritzkes, DR. Clinical Implications of Antiretroviral Resistance. HIV Clinical Management - Volume 13. © 1999 Medscape, Inc.



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***Continued from page 19***

infected CD4+ cells to die off, thus eventually eliminating HIV reservoirs from the body. However, numerous studies have demonstrated that latently-infected CD4+ cells persist for a longer period of time than initially projected, and that viral replication continues at low levels despite responses to HAART therapy. Scientists now estimate that with currently available therapies, it may take 12-60 years of persistent viral suppression to eradicate HIV from the body. Researchers are therefore increasingly focusing their efforts upon immunologic strategies in the fight for a cure. The body's own defense mechanisms are increasingly recognized as contributors in destroying CD4+ cells, resulting in immune destruction and opportunistic infections. Immune-based therapies are hoped to restore and enhance host immunity, increasing the body's ability to fight HIV and other pathogens.

Although early work with HIV envelope-subunit vaccines such as gp120 and gp160 did not prove effective in clinical trials, vaccination strategies continue to be explored. Remune is an envelope-depleted HIV protein matrix complexed with Incomplete Freund's Adjuvant (IFA) which, when injected induces lymphocyte proliferation to HIV core antigens. Early clinical trials comparing Remune to control (IFA) indicated that Remune vaccination was associated with significant improvements in HIV-specific lymphoproliferative responses compared to control. In addition, the response level among those receiving Remune was similar to levels reported previously among long-term non-progressors, and Remune therapy was associated with a trend in more durable virologic suppression. [8]

Results of a large, randomized, placebo-controlled study of Remune in HIV-infected patients with 350-500 CD4 cells/$mm^3$ were recently presented and, unfortunately, indicate that while vaccine recipients exhibited significant increases in lymphoproliferative responses to HIV and p24 antigen, vaccination did not significantly affect rates of clinical disease progression or virologic suppression. Mild increases in CD4+ cell count (+16 cells/$mm^3$, $p<0.01$) were associated with Remune therapy in this study. Low rates of disease progression in each study arm demonstrate the beneficial effects of HAART, which all subjects were allowed to continue as part of routine care. [9]

Interleukin-2 (IL-2) is another immunomodulator being studied for its ability to promote immune system function and recovery. IL-2 is a cytokine that may be associated with an increase in CD4+ cells, reversal of abnormal cellular activation that can lead to immune destruction, and improvements in immune system functions such as antigen processing and beneficial cellular activation. Because of its immunomodulating effects, treatment with IL-2 may be associated with hypotension, flu-like symptoms, lethargy, renal dysfunction, dyspnea, and pulmonary congestion. These effects and a requirement for parenteral administration (intravenous or subcutaneous) may limit widespread use of the drug.

Results of several studies of IL-2 in combination with antiretroviral therapy have demonstrated elevations in CD4+ cell count compared to control groups who received antiretroviral therapy alone. In these studies, IL-2 was most commonly administered subcutaneously and intermittently to patients with at least 200 CD4 cells/$mm^3$. Several additional clinical trials are underway to further study the effects of IL-2 therapy in those with more advanced HIV disease.

## Conclusions

In summary, management of patients infected with HIV continues to be complicated and fraught with challenges such as adherence, treatment-associated toxicities, and serious drug interactions. The optimism of the mid -1990's with the advent of the protease-inhibitor era and discussion of virus eradication has been replaced with a recognition of the many limitations of HAART therapy and renewed dedication to study alternate treatment strategies. These strategies include protease-sparing regimens, scheduled treatment interruptions, resistance testing, and immune-based therapies. As we enter the new millennium, we remember the friends and family we have lost to this devastating disease and continue to help our patients fight for a cure. ◉

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# KERR DRUG - ENHANCED PHARMACEUTICAL CARE CENTER

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by: Ami Teague Deaton & Emily Murray

### Describe your overall practice.

The Enhanced Pharmaceutical Care Center (EPCC) is a collaborative effort between Kerr Drug and the University of North Carolina School of Pharmacy. The mission of the EPCC is to demonstrate the benefit of pharmaceutical care services to patients, pharmacists, pharmacies, prescribers, healthcare payers, and the pharmaceutical industry. It is a laboratory for practitioners, faculty, and students to develop and implement sustainable models of pharmaceutical care practice.

The physical design of the EPCC conveys the visual message that this is a pharmacy of the future. A 1000-sq. ft. clinic adjacent to the traditional dispensing pharmacy, the EPCC is comprised of semi-private rooms for patient consultation, a classroom for patient educational programs and inservices, a resident workstation, and reception area. Staffing includes a full- time coordinator/shared faculty position with the University, full-time community pharmacy resident, as well as part-time contributions from three Kerr pharmacists and three faculty members from the School of Pharmacy, all of whom collectively provide one additional full-time equivalent. Many students are actively involved in EPCC activities through clinical clerkships, independent studies, clinical lab curriculum requirements, or as volunteers.

The EPCC is a wonderful example of what can be accomplished when the disparate worlds of chain pharmacy and academia combine their human and fiscal resources in the best interest of patient care and the profession of pharmacy.

### How did you determine the needs? How did you develop your practice to meet these needs?

Before the opening of the Center in September of 1998, an extensive analysis of morbidity and mortality data for Orange County was performed. In addition, a query of the pharmacy database was conducted to determine frequently dispensed medications. In addition to these two objective methods, patient input was strongly considered in determining the program and service menu of the EPCC. Offerings have also been added based upon collaborative relationships with local health providers and agencies.

A planning team with representatives from both Kerr and UNC was utilized to bring the EPCC into fruition. Programs were developed according to national protocols, and individual EPCC staff became responsible for specific disease state programs.

*A patient recieves a flu vaccine during the EPCC/Orange County Health Department Adult Immunization Clinic.*

### Unique services provided.

Three focus areas exist for the provision of services at the EPCC: prevention, detection, and monitoring/management of chronic disease. Care is delivered by appointment, with walk-ins permitted where possible. Prevention programs include influenza and pneumococcal vaccine clinics; an educational lecture series offered on Monday mornings where patients can gather for presentation of a health topic by an area expert along with continental breakfast; a smoking cessation program including workshops, one-on-one pharmacist care, and support groups for those who successfully abstain; and soon-to-be added weight management program.

A variety of screening services is routinely offered at the center. These include measurement of: bone mineral density, intraocular pressure, blood pressure, blood glucose, lipids, hemoglobin, and hemoglobin $A_{1c}$. Patients are often referred to an appropriate healthcare provider as a result of EPCC detection services. Soon to be added in this area are: prostate specific antigen testing (PSA), spirometry, body mass composition, and arterial elasticity.

EPCC Patient Care Programs are designed for the

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NORTH CAROLINA SOCIETY OF HEALTH-SYSTEM
NCSHP
PHARMACISTS

Newsletter

Volume 22, Number 6 The bimonthly publication of the North Carolina Society of Health-System Pharmacists November/December 1999

*From the President*

# Accomplishments and Challenges

NCSHP members who participated on committees, task forces and NCSHP Board were very active this year and should be very proud of our accomplishments. We were challenged to fulfill NCSHP goals and member needs and to create the foundation of a new pharmacy organization in North Carolina to take the profession into the next century. NCSHP Committee Chairs completed committee reports for review at the NCSHP Board meeting on October 5, and highlights were presented at the NCSHP Business meeting held on October 6, at the Annual Carolina Seminar in Greensboro, N.C.

*NCSHP President William L. Harris, Jr.*

I would like to thank each of the following NCSHP members who served as Chair or Co-Chair of a NCSHP committee or NCAP task force: Beth Williams, Regina Schomberg, Karen Petros, April Cooper, Mike Soucie, Anna Garrett, Chris Jones, Alice Foust, Laurie McElhone, Jill Garris, Lori Wilson, Apollo Lin, Amanda Greenwood, Mark Ninno, Ken Burleson, Chris Lehman, and Tim Giddens. In addition, I would like to thank Frances Gualtieri, who served many years as NCSHP Administrative Director, for agreeing to serve as NCSHP Historian.

Their enthusiasm, dedication and leadership, like that of countless others over the years, have made NCSHP a visible and successful organization. We have an opportunity to continue this tradition of service and leadership to all pharmacists in North Carolina through our participation in our new organization, the North Carolina Association of Pharmacists (NCAP). Vance Collins will serve as Chair of the Acute Care Practice Forum, which will endeavor to serve the needs of health-system pharmacists in the new organization. Vance welcomes your input and participation in the Practice Forum.

Now is the time for renewal. When you receive your membership notification, please join your friends and colleagues in NCAP. The profession needs your support and participation.

## NCAP Three-Year Strategic Plan

Approximately sixty pharmacy leaders gathered in Greensboro, N.C. on October 21, to create a three-year Strategic Plan for the North Carolina Association of Pharmacists (NCAP). These pharmacists came from all areas of the state and represented many different practice sites. There was enthusiasm, determination and excitement in the air as we reviewed the NCAP mission and vision statements and the strategies of the new organization to serve and advance the profession of pharmacy in North Carolina.

Through a combination of group meetings and break-out sessions, a three-year strategic plan evolved. The following goals were established to guide NCAP in fulfillment of our mission. Please read these goals and visualize where our profession and individual practices will be in three years if we accomplish these objectives.

Goal 1. Increase participation through retention of current members and recruitment of new practitioners and students.
Goal 2. Serve the educational and professional needs of distinct pharmacy disciplines in meeting the NCAP mission of uniting, serving, and advancing the profession of pharmacy for the benefit of society.
Goal 3. Affiliate with all local associations and ensure that all NCAP members have a local affiliate.
Goal 4. Create and continuously strengthen organizational relationships with other health professions and related constituencies.
Goal 5. Assess the needs and develop strategies for improving and facilitating the role and utilization of technicians.
Goal 6. Expand the number of traditional and non-traditional pharmacy residency training opportunities in North Carolina.
Goal 7. Develop fiscal responsibility for maintaining and expanding the financial base to support growth and development of the Association.
Goal 8. Promote the growth and development of pharmacy leaders in North Carolina.
Goal 9. Increase the number and diversity of advanced pharmaceutical care providers throughout the state and aid in the establishment of a data collection repository for pharmaceutical care interventions.
Goal 10. Develop and implement marketing strategies to the general public to communicate the value that pharmacists add as a part of the healthcare team.
Goal 11. Enhance professional relationships, legislative awareness, lobbying, and communication efforts to pursue and pass key legislative issues to maintain pharmacy as a viable and profitable profession.
Goal 12. Increase the number of pharmacists who are professionally satisfied and focused on health care outcomes. ◎

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NCSHP members are encouraged to share their views, concerns and ideas with their colleagues by contributing articles to the NCSHP Newsletter. Opinions expressed are those of the author and may not represent the views of NCSHP, its officers, Board of Directors or its membership. Copy deadlines are the 10th of the month prior to the month of the next issue to be published. (i.e. April 10th for the May/June Issue.)

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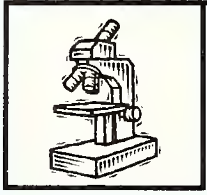
## *Clinical Consultants Corner*



# HYDROXYUREA FOR THE MANAGEMENT OF HIV

by: Tiffany C. Phillips

The therapeutic management of HIV-positive patients has become a considerable challenge for health care providers. Despite the availability of effective therapies, the emergence of resistant viral strains has greatly complicated selection of optimal therapies.

Since the first case of HIV in the early 1980s, medical management has progressed from a single agent to the current multiple drug regimen. The nucleoside reverse transcriptase inhibitor (NRTI) zidovudine was the first FDA approved antiretroviral agent. Nonnucleoside reverse transcriptase inhibitors (NNRTIs) and protease inhibitors (PIs) were later developed. Optimal therapy requires adherence to the prescribed regimen as well as continuous patient education. The most recent guidelines for management of HIV infection in adults and adolescents recommend offering treatment to those with less than 500 $CD_4$ cells or plasma HIV RNA greater than 20,000 copies as measured by RT-PCR.[1]

The currently recommended antiretroviral regimen includes the use of two NRTIs and one PI. When a regimen results in failure, the ideal approach is to select a new regimen with three different agents that do not display cross-resistance with previously used drugs.[1] Often this approach is not feasible among individuals with advanced HIV disease who have exhausted most of the possible drug options.

Despite the positive results seen with current therapy, the approved regimens have several drawbacks. Frequent daily dosing with multiple tablets or capsules, consideration with regard to meals, drug-drug interactions, cost, and significant adverse reactions are the most problematic. Research to develop more tolerable antiretrovirals is warranted.

Hydroxyurea has been studied for its potential role in treating HIV, particularly in combination with NRTIs. Hydroxyurea has been in use for approximately three decades for the management of various forms of cancer and, more recently, sickle cell disease.[3] Hydroxyurea inhibits the rate-limiting cellular enzyme, ribonucleotide reductase, responsible for the synthesis of deoxynucleoside triphosphates (dNTPs).[4] By inhibiting dNTP, HIV DNA synthesis is inhibited. Even though the total pool of dNTPs are reduced, the specific nucleotide dATP (deoxyadenosine triphosphate) seems to be more sensitive to hydroxyurea's effects.[2]

A synergistic effect has been observed with didanosine (ddI) and hydroxyurea in earlier in vitro studies. Didanosine, which is converted intracellularly to the active metabolite ddATP (dideoxyadenosine triphosphate), competes with dATP for binding sites on reverse transcriptase. DDATP also stops DNA chain synthesis by inserting itself into the DNA rendering cell death.[2] Thus, ddI has been studied in combination with hydroxyurea providing results that support a decrease in viral counts. Other NRTIs in combination with hydroxyurea have been researched with less favorable results.

To date no large multicenter studies have been conducted. However, several smaller studies support the potential benefits of hydroxyurea in decreasing viral loads in adults with HIV. Most studies have included hydroxyurea in combination with ddI. Significant decreases in viral load were observed with a decline in $CD_4$ cell counts in most studies.[5,6,7] Hydroxyurea was well-tolerated

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# TECHNICIAN PRACTICE FORUM: THE BEGINNING

October 15, 1999, will be remembered as a historic day for North Carolina pharmacy. On that day, the following pharmacy leaders came together at the Institute of Pharmacy in Chapel Hill to discuss the role of technicians in the new state pharmacists organization: Jane Younts, Ken Burleson, Jana Andrews, Bill Post, Dean Strahm, Jack Watts, Lynne Alexander, John Burnett, Jim Hickmon, Don Kritsch, Joe Anne Griffith, Angie Wagner, Dan Garrett and Teresa Devora.

Jane Younts called the meeting to order at 10:00 a.m. She explained the purpose of the meeting and distributed an agenda. Since this was the first meeting for the group, there were no minutes of previous meetings.

Jack Watts, of the NC Board of Pharmacy, circulated a document entitled Registration of Pharmacy Technicians, which has been presented to legislative bodies. Jack discussed problems of passage of the bill, due to resistance from a particular legislator. Jack said that NCAP will have to introduce the bill into the Legislature through sponsorship support.

Dan Garrett pointed out that we have no representative from chain drug stores on committee and said he plans to pursue adding a chain member. Dan distributed a White Paper developed by NACDS, APhA, and NCPA entitled "Implementing Effective Change in Meeting the Demands of Community Pharmacy Practice in the United States," published in August, 1999. This paper detailed use of pharmacy technicians as one method to meet future demands. This is significant since NACDS is taking a positive position on use of technicians.

The Practice Forum also discussed GAPTAB, the Greensboro Area Pharmacy Technician Advisory Board. This group is made up of equal numbers of pharmacists and technicians from Greensboro, and chain pharmacies are represented. The group has a program through Dudley High School, developed by Alice Foust, which introduces selected students to pharmacy technology as a career. Students are selected by competitive process and given a one-semester didactic program. They are then placed at community sites for a semester rotation. They may sit for the certification exam once they graduate. Many students decide to go on to pharmacy school, while others get positions primarily in community pharmacies, where starting salaries are approximately $22,000.

Don Kritsch discussed Community College Training Programs for pharmacy technicians. Programs now offer the equivalent of a one-year degree, using semester format. There are seven active programs in the state, and enrollment is increasing. Some chains have approached the colleges with specific requests, but most chains have left relations with community college programs to the district managers. NCAP may need to concentrate efforts on these individuals. There is a national organization representing community colleges in pharmacy technology training.

The group also discussed problems with pay scale. Graduates of other technical programs from community colleges are offered higher paying jobs. John Burnett explained that other technicians (surgical, radiological, etc.) are licensed, self-regulated, and students make more money. Bill Post discussed how community colleges would likely work to "grandfather" technicians who have on-the-job-training with no schooling if training and certification become mandatory. Bill also expressed frustration with third-party insurance reimbursement hampering the ability of stores to pay higher salaries to technicians. Salaries at various locations were discussed. One hospital is low compared to other similar job categories; another hospital's new scale starts at $9.71 per hour and goes to $15.00 per hour. Quotes for chain drug stores ran from minimum wage up to $15.00/hr. Salary disparity was recognized as a limiting factor.

The group also considered who might be appropriate members to serve on committees and task forces that address pharmacy issues. These individuals will be contacted by Jane Younts to determine interest in service:

**Technician Practice Forum**

| | |
|---|---|
| Education: | Michelle Poarch, technician |
| | Jim Hickmon, pharmacist |
| Legal & Regulatory: | Faye Elliott, technician |
| | Jack Watts, pharmacist |
| Membership: | Crystal Ellen |
| | Laurie McElhone |
| Professional Relations: | Marion Keener, technician |
| | Dean Strahm, pharmacist |

**Committees to be formed within Technician Practice Forum**

| | |
|---|---|
| Education | Angie Wagner, Chair |
| | Laurie McElhone |
| Legal and Regulatory | Michelle Valentine, chair |
| | Joe Ann Griffith |
| Nominations | Sandra Covington, chair |
| | Colleen Gresham |

For more information on Technician Issues, contact NCAP at (800) 852 7343.

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overall. Limited abstract data reports the use of hydroxyurea and ddI in combination with a protease inhibitor. Viral load reduction was observed even to undetectable levels in some patients.[8]

Hydroxyurea as monotherapy has not resulted in viral load reduction or improvement in disease status. $CD_4$ cell counts remained unchanged or slightly declined.[9] At this time, monotherapy cannot be advised.

If the decision to begin therapy is made, baseline viral loads, $CD_4$ cell counts, CBC with differential, and renal and hepatic function should be determined. Due to the potential to decrease $CD_4$ cell counts, hydroxyurea should be used with caution or perhaps avoided in patients with a low $CD_4$ cell count. Hydroxyurea should not be initiated if a patient's absolute neutrophil count is < 1700 cells/mm$^3$ due to the increased risk of neutropenia. Laboratory markers should be evaluated every 3-4 months.[10]

The cellular enzyme, ribonucleotide reductase, does not appear to undergo mutations thereby possibly preventing resistance to hydroxyurea.[2] The usual starting dose is recommended as 500mg twice daily, which is significantly less than doses for other disease states. Possible side effects include myelosuppression, rash, nausea and vomiting, mucositis, and hepatitis which could further complicate the side effects of other antiretrovirals.

Even though hydroxyurea has demonstrated antiretroviral activity in smaller studies, larger controlled multicenter trials are warranted to determine dosage, efficacy, adverse events, and drug interactions with long term treatment. The literature suggests that combination therapy with hydroxyurea and ddI is more efficacious than hydroxyurea monotherapy. At this time, hydroxyurea should be a last resort for patients who are not responding to or cannot tolerate their regimen.[2] Further evaluation will determine its role in the challenge of managing this complex disease. ◉

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monitoring and management of chronic disease. They currently include: asthma, diabetes, dyslipidemia, hypertension, and osteoporosis. Frequency of appointments and length of program vary by disease state. Individual program elements are determined by nationally accepted protocols for treatment and are tailored to meet individual patient needs. Our staff, with the help of Herb Patterson, PharmD, and UNC Cardiology Fellow, Jo Ellen Rogers, PharmD, is currently working to design and implement a care program for patients suffering from heart failure.

The following services are also routinely provided: consultations regarding natural products/complementary medicine; workshops for caregivers of patients with cancer; and "brown bag" medication reviews. In addition, the EPCC is involved in grant-funded outcomes research and demonstration projects with third-party payers, as well as the Community Diabetes Initiative being coordinated by NCCPC.

### Reimbursement

The population served by Enhanced Pharmaceutical Care Center is relatively affluent. As a result, most patients are willing and able to pay directly for the services rendered at the EPCC. Program support is also provided through unrestricted educational grants. Professional fees are fixed for screening services, but vary for disease state management services depending on the time and level of intensity required.

### Challenges

1. Dispensing activities remain a very necessary component of pharmacy practice and must be integrated, as seamlessly as possible, with the provision of expanded clinical services. It is difficult, but essential, to coordinate these two different worlds without sacrificing the quality of either. Time spent counseling patients on their medications must be viewed as a means to identify need and generate referrals for EPCC clinical services rather than an end.

2. The operational aspects of pharmacy also present a challenge. The tremendous, growing volume of prescription medications dispensed, coupled with the short supply of pharmacists to fill them, challenge our commitment to provide pharmacists with time expressly dedicated to disease state management.

3. Even pharmacists with a proclivity for direct patient care may need considerable re-tooling if they have been practicing outside the pharmaceutical care mainstream. Resistance to change and doubt in the proficiency of one's own clinical skills can be overcome. Thorough training including case management, regular evaluation, and incentives are vital components of staff development.

4. Perhaps the biggest challenge we have faced and still face is changing the mindset of our consumer. It is quite a leap from viewing the pharmacy as a place to get pills to accepting it as an outlet for the provision of healthcare. Our most persuasive tool is the demonstration of value and quality of care. Effective marketing of this tool, by way of personal selling to all of our stakeholders, has been the key to our success to date.

### Where are you headed now?

Since opening in September of 1998, more than one thousand patients have received quality care at the EPCC. We have provided quality care and have been compensated for our professional services. Our focus moving forward will be on using our performance history and the relationships we have established with self-insured employers and other third parties to shift the source of our compensation. Patients and area health care providers have consistently expressed satisfaction and confidence in our services, as well as a realization that the center is, in many cases, meeting needs previously not addressed by the healthcare community. It is our goal to strengthen and grow relationships with these two groups through continued marketing and quality care.

The EPCC has been successful in cultivating collaborative relationships with several local and state organizations such as the health department, the NC Department of Health and Human Services, March of Dimes, NC Prevention Partners, and the Orange County Asthma Coalition. In addition, legislative activity of EPCC staff members helped to provide support of the passage of the Bone Mass Measurement Bill this summer. We believe that by continuing to build community relationships, we will help to elevate public perception of the role of the pharmacist as a central, rather than tangential, member of the healthcare team.

Perhaps one of the most significant accomplishments of the EPCC is the way in which student involvement is actively encouraged by staff members and eagerly sought by the students themselves. This is certainly an area that we will work to grow and strengthen. UNC School of Pharmacy students have the opportunity to satisfy certain course requirements, complete clinical clerkships, and explore independent study or honors program projects at the EPCC. In addition, many students simply volunteer their spare time to help perform administrative and certain patient care activities.

The EPCC is very proud to be the home of an APhA/ASHP-affiliated Community Pharmacy Residency Program. We will be applying for accreditation through ASHP within the next year. We believe that residency programs are our bridge to the future—expanded clinical services in the community pharmacy setting.

The EPCC in Chapel Hill is the first of several patient care centers that Kerr Drug plans to develop within its chain of stores over the next year. ◎

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## Changes to Continuing Education

In order to better serve our members, the *Carolina Journal of Pharmacy* will be mailing a special CE Supplement only to members who request it. CE will no longer be published in the *Journal*, leaving more room for news of interest to all readers. As always, Continuing Education is available only to members.

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Members who would like to be added to the mailing list for CE should contact Teressa Reavis at teressa@ncpharmacists.org or (800) 852-7343.

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# Letter to North Carolina Pharmacists

*The following is a letter sent by independent pharmacist Bill Mast to his customers.*

First we would like to say thank you for the opportunity to serve you and your loved ones for your prescription needs. Secondly, we greatly desire to continue our dependable and courteous service to your family.

Blue Cross has recently reduced their reimbursement to us for filling a prescription to levels we cannot accept. They do not pay us close to what our operating cost is to fill a prescription. The only way for us to survive if we accept their rate would be to charge the elderly uninsured enough to make up for what we loose on Blue Cross prescriptions. Blue Cross does not insure people on Social Security over 65 years old, except with supplemental insurance. Most people over 65 years old cannot afford supplemental insurance. We cannot burden those people, so we must not sign the Blue Cross reimbursement.

What are we to do? As stated in a letter you received from your carrier, "you may choose to use a nonparticipating pharmacy." We will gladly fill your prescriptions and will continue to file your insurance claim, as we have for many years. Reimbursement from your carrier will come back to you. We will price your prescriptions at the same rate the state allows us to charge the state welfare (Medicaid) customer. That fee is $5.60 per prescription. We as a company also have the same insurance carrier for health insurance for our employees. Effective December 1, 1999 (our renewal date) we will no longer support a carrier that continues to increase premiums and decrease service.

Again, we thank you for the years of support and patronage. We hope to continue serving you and your family for years to come. We also encourage you to call your carrier and voice your opinion. You are their customer. Your premium is what pays them. Their phone number is (800) 437-7458.

Thank you and we hope to see you again soon.

Sincerely,

Bill Mast, Mast Drug Company, Henderson, NC

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To the Editor:

Many people do not expect disaster to hit. People are often unprepared. Pharmacists should be aware that disasters can strike a pharmacy without notice just as easily as a beach house or other business. A disaster can be in many forms such as hurricanes, fire, tornadoes, floods, power outages and even break-ins. These situations can cause financial and health challenges for owners and customers. Pharmacy managers in North Carolina are responsible by law to have a plan in case of natural disasters occurring which affect the pharmacy.

In this day and time a normal insurance policy on a pharmacy is a necessity because of law suits filed by people because of accidents and also in case of disasters. Without insurance a pharmacist is at risk of losing everything with one mistake or weather change. Most plans insure all the store's contents, including drugs and equipment and store merchandise in the case of a natural disaster or break-in. Damage caused by war is usually not covered. For maximum reimbursement the pharmacist should keep a record of all stock and equipment, including the worth of each item. This includes computer hardware, along with the make and model number. Insurance adjusters, who review these situations, have a much easier time reimbursing the correct amount to the pharmacy if a list is ready when the disaster occurs(1).

Insurance policies usually require that after a disaster the pharmacy is protected as best as possible from further damage. For example, if the roof was blown off, a tarp or cover should be placed on the roof as soon as possible to prevent further water damage.

Policies often include coverage for circumstances that could occur such as pharmacist mistakes, customer accidents while in the store, or interrupted business due to uncontrollable circumstances, such as natural disasters or break-ins. Professional liability is the plan that covers pharmacists in case they get sued for a filling or dispensing error. An example is causing bodily harm to a patient by giving a medication different from what the physician prescribed. Liability is coverage in case a customer sues because they slipped on the wet floor that had just been mopped and there was no sign saying "Caution: Wet Floor." Interrupted business is reimbursement to the pharmacy for business they lost while being closed for repairs or because they could not open due to low stock because of theft. This usually has a monthly limit. Some plans have a 12-month limit. A policy including all this coverage is good to have with all the problems a pharmacist faces these days. Especially in independent pharmacies, where there is a sole owner whose livelihood is their pharmacy business, full coverage is almost a necessity.

**General Disaster Plan:**

1. Keep the computer records on disks either in a fire-safe box or take them home nightly. This will enable the pharmacist to reboot the files in another location to fill prescriptions. It is good to have more than one copy. A suggestion is to save on one set on Monday, Wednesday and Friday and another set of disks on Tuesday, Thursday and Saturday. This way there will be two copies to keep in two separate locations.
2. Have a plan to relocate in a temporary location in case a disaster causes the pharmacy to be inaccessible.
   ***Option 1***: A mobile home is the usual option. Some states, such as Virginia, only allow the use of a mobile home for a set time. This is because break-ins are easier in mobile homes.
   ***Option 2***: Use another pharmacy's facilities and stock until another location is available.
3. Make sue to let customers and physicians' offices know of the change in location and phone number. The newspaper, fliers, and telephone calls can be useful for this announcement.
4. Keep inventory list to give to insurance agent for faster reimbursement.
5. Get estimates for repair as soon as possible so repairs can be started.
6. If physicians' offices are not open, give maintenance medications according to the state law. Try to call physicians at home first.

Julie Ann Alston
UNC-CH School of Pharmacy – B.S. Program
Community Pharmacy Externship

# Classified Advertising

## EMPLOYMENT

Live on the Crystal Coast of Morehead City and Atlantic Beach N.C.! Carteret General Hospital has two staff pharmacist positions available immediately-day/evening rotation or night shift(7 days on / 7 days off). Join a progressive, teamwork-oriented staff in this public, not-for-profit 117-bed facility. Cancer Treatment Center services, teaching, multi-disciplinary rounds and telemedicine contribute to expanded professional roles for new graduates or experienced pharmacists. Excellent salary and benefit package. Significant sign-on bonus and relocation allowance provided. Live where most people go for vacation! Submit resume or call Beth Beswick, VP Human Resources at 252-247-1531, FAX 252-247-1335. e-mail bbeswick@ccgh.org. EOE

PHARMASTAT IS LOOKING for select pharmacists with the flexibility and skills to join our staff of relief pharmacists. We can offer you new skills, extra income, 401(k) participation, flexibility and the backing of a solid professional organization. To take advantage of this opportunity, call (800) 252-7828.

PHARMACIST WANTED: Individual will be responsible for Provision of Pharmacy Care to include both Distributive and Clinical Services. Duties include target drug therapy monitoring, anticoagulation, pharmacokinetic services and drug therapy management under Collaborative Protocols. Qualified candidates may be placed on Clinical Pharmacist Track. Requirements include B.S. Pharmacy or PharmD with institution experience; Pharmacy Practice Residency preferred. Salary range from $65,500 to $73,275 with excellent benefits, including major medical insurance, dental insurance, paid time-off, pension plan, Credit Union, SRMC fitness center and much more. Qualified candidates should send or fax resume to: Durham White, Assistant HR Director, Southeastern Regional Medical Center, P.O. Box 1408 Lumberton, NC 28359. Fax: (910) 671-1757 E-mail white01@srmc.org Web Site: www.srmc.org. An Equal Opportunity Employer.

INFECTIOUS DISEASE SPECIALIST: Mission St. Joseph's Health System is searching for an infectious disease pharmacist. This pharmacist will coordinate an antibiotic advisory program within our health system. The pharmacist would work directly with Infectious Disease physicians, microbiology, Infection Control, and Pharmacy to promote optimal antibiotic plans. Qualified candidates must have a Doctor of Pharmacy degree from an accredited School of Pharmacy and 2-3 years experience in infectious disease and antibiotic management. Completion of an ASHP-accredited residency preferred. Please send Curriculum Vitae with cover letter to: Mike Wooten, Pharm D., BCOP, Clinical Manager, Department of Pharmacy, Mission St. Joseph's, 428 Biltmore Ave., Asheville, NC 28801.

THE MOSES CONE HEALTH SYSTEM has a full-time clinical pharmacist position available. Moses Cone is a 547-bed community teaching hospital located in Greensboro, NC. As a quality health care provider in our community, focus is on designing our emerging health system to meet the medical and pharmaceutical needs of our patients. MCHS pharmacists are involved in patient care. Through our drug management services, pharmacists have prescriptive privileges in the areas of anticoagulation, antibiotics, nutrition support, and other areas. Primary aspects of the position include being a clinician, preceptor for residents and students, decision-maker on path, and supervisor for the distribution system.
Benefits include working every 5th weekend, 25 days of paid annual leave, medical and dental coverage, an on-site day care center, and tax-deferred annuities. Greensboro is centrally located between the beaches and mountains. Candidates with clinical training and experience in the acute care setting are encouraged to apply. For more information, please call Donna Harris, Corporate Recruitment at (336) 832-7089 or 1-800-476-6737 or email at donna.harris@mosescone.com. Come join our crazy team! EOE

STAFF PHARMACIST is needed at Murphy Medical Center. Murphy Medical Center, a 50-bed hospital and 120-bed nursing home serving beautiful Southwestern Counties of North Carolina, has an immediate opening for a full-time staff pharmacist. Murphy Medical Center is a dynamic organization enjoying significant growth. Successful candidates must be licensed in North Carolina. Experience with computerized pharmacy preferred. To apply, send resume to: Murphy Medical Center, Human Resources Dept., Atten. Steve McDonald, 4130 Hwy. 64E., Murphy, NC 28906 or call (828) 837-8161 ext. 536.

## FOR SALE

PHARMACY FOR SALE: If you're reading this ad, we should talk. You're either not satisfied with your current situation or you're looking for an investment. If you've been considering owning a pharmacy, but are hesitant to start from scratch, here's an opportunity to purchase an established, perscription-oriented pharmacy in Alamance County. Most people can afford their own business... we can show you how. Please call John Aumiller at (800) 325-1397, ext. 5383 for more details.

## SERVICES

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*Closing date for classified advertising is the 15th of the month preceding publication. Ads (up to 50 words) are free for current NCAP members if indicated when placing the ad. The non-member rate is 75¢ a word with a $25 minimum. Send ads and billing information via fax to (919) 968-9430 or via e-mail to journal@ncpharmacists.org.*

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